From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/26/2021 7:29:46 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]; Harris, Claire (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4b5754f95cf44f8a2655beda3899166-harriscl]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

No prob. Will do after 3.

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 2:29 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Yikes! I just realized I wasn't clear! Claire was fine with you sending to Tara and ccing us. I am so sorry.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 2:17 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >; Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK—here is a clean version. Claire, can you remind Tara that Michelle and I are reporting to Dr. Tabak on ACTIV issues and tell her that FNIH asked the two of us to look at whether there were problems with their proposal? From the earlier emails, I couldn't tell if she knows & I don't want to get wires crossed.
Thanks,
Ellen

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Sent: Friday, February 26, 2021 1:45 PM
To: Gadbois, Ellen (NIH/OD) [E] · b6 Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] · ; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi—Claire and I reviewed and just a few further edits (mostly spacing and taking periods out of third column for consistency-or you can have all periods). Also, I can't believe I didn't remember that if the FACA bill is enacted, we can say goodbye to workgroups as well. So, I made a note in that column.

Per your Q below, Claire asked to send to Tara first and cc all of us.

Thanks so much!

Patti

From: Gadbois, Ellen (NIH/OD) [E] <b6>
Sent: Friday, February 26, 2021 1:01 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <b6>; Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks Patti & Claire. I accepted the existing edits and made a few modifications for formatting. I also changed "grantees" to "awardees" in a few places for consistency. Those changes are all in redline still.

Patti—re. your question about using ACD/CoC for this sort of thing—I think they already went down that road with the HeLa WG for the ACD, so I didn't put in that angle as a con.

I'll clean this up next and send around the clean one. You all should let me know if you see any remaining issues.

Claire—do you think Tara wants to see this before it goes to LT? I am happy to send it to LT if you think it can go now (or after meeting with Tara Monday) and I would cc Tara & all of you folks...

Thanks again,
Ellen

From: Brandt Hansberger, Patricia (NIH/OD) [E] <b6
Sent: Friday, February 26, 2021 12:10 PM
To: Gadbois, Ellen (NIH/OD) [E] <b6
Cc: Culp, Michelle (NIH/OD) [E] b6 Harris, Claire (NIH/OD) [E] <b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-I am ccing Claire since we are on the home stretch (I hope!) of finishing this up.

I spoke to Claire and added some minor edits and notations. I added a couple of "cons" but I don't know if they really qualify.

Claire is fine if you send the pro/con document and cc everyone as you most familiar with the ACTIV FNIH activities, know the players, have the background, etc.

If you have a sense of when you think you'd be done, that would be great. Claire has her standing meeting on Monday with Tara.

Please let us know if you have any Qs or need clarity on anything!

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 11:40 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <b6
Cc: Culp, Michelle (NIH/OD) [E] <b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I would choose the ACD because they are used to dealing with data access requests coming through the ACD HeLa Working Group.

From: Brandt Hansberger, Patricia (NIH/OD) [E] <b6
Sent: Friday, February 26, 2021 10:58 AM

To: Culp, Michelle (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes – Just got out of one meeting with Claire and headed into another. I showed her the document and she wanted your opinion of which committee would make more sense for this work group, the ACD or the CoC. Knowing a working group concept isn't optimal, she still wanted to get your thoughts. I will have a couple of edits to the work group row based on my discussion with Claire.

P

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 10:21 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen,
I reviewed your edits to the document. Thanks for adding the "as proposed by FNIH" to the section headers and for clarifying text in the table. Much better!

Patti,
If your hand is on the document now, I think you can remove the 2nd column since Ellen made it better as the 1st column.

Thank you!
-Michelle

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 9:37 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ah – you beat me. I'll add to your edits.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 9:36 AM
To: Culp, Michelle (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks very much, Michelle. I made some proposed edits.

Note that I'm suggesting we delete what was formerly the first column and replace with something a little more comprehensive.

One key thing based on my understand of our PPP structures & FNIH steering committees—FNIH/the ACTIV Steering Committees can't actually advise NIH—the Steering Committee can only advise the grantees. (Somehow it works out.) And as long as the ACTIV Steering Committee only advises grantees, it seems like grantees would make the final decision of who gets what, so there's an out here if the grantee doesn't want to follow the ACTIV advice and/or for NIH to get involved.

Finally, b5
b5

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,
I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >; Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] < b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

From: Martin, Ann (NIH/OD) [E] < b6
Sent: Thursday, February 25, 2021 9:10 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 ; Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
2:30 works best for me today, if that still works on your end.

For your consideration in the meantime, (b) (5) We are not aware of committees that fall into that "operational" category in the absence of a statutory basis for such a role. It is hard for me to see "operational" as an option for the biospecimen committee. It is correct that the sharing of information in a group setting between federal officials and experts does not implicate FACA. The important aspect in such a scenario,

however, is that it be grounded on an exchange of information. The non-government participants would not have an advisory role. This is different than an "operational" committee within the meaning of "operational" for purposes of the FACA regulations. It doesn't seem that the "information exchange" setting will suit NIH's/ACTIV's needs here, but I would be happy to explore this further with you.

I have also made a few notes below in red.

Happy to discuss this afternoon.

Thanks,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 7:55 PM
To: Martin, Ann (NIH/OD) [E] b6 >
Cc: Gadbois, Ellen (NIH/OD) [E] < b6 ; Culp, Michelle (NIH/OD) [E] < b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Ann! Tara and Larry want us to lay out all the options in one email which I am working on with Ellen and she would like to have one more chat and wants to understand more how DSMB's work in particular. I took a crack at starting something (see directly below) and Ellen is going to start wordsmithing this tomorrow. Our goal is to keep this as concise as possible.

I know this is short notice, but wondering if you were available any of the times below tomorrow?

- 9:00
- Noon
- 2:30

FACA Options:

(b) (5)

(b) (5)

Non-FACA Options:

(b) (5)

(b) (5)

From: Martin, Ann (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 3:55 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
Thanks for the info below. I would be glad to talk with you and Claire about this on Monday. Would 11:30 or later work ok?
Hope you are doing well!
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 2:07 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good afternoon. I am working with Claire on an ACTIV issue. Per the email trail below, (b) (5)
(b) (5)
The committee would be comprised of ACTIV trial team members, academic, and industry representatives who would set review and prioritization criteria, assess biospecimen requests, and recommend which ones should be reviewed by an oversight committee (see slide 6). Claire and I had a conversation with Ellen Gadbois and Michelle Culp yesterday about possible options if NIH were to form such a committee. The email Ellen sent to LAT below is based on that conversation.

The email exchange contains several ideas and Claire wanted your thoughts on the following idea from Tara:

b5

I just had a chat with Claire, and this wouldn't be a subcommittee or a workgroup of a full committee; it seems like something different. Claire wants to know if Tara's idea raised any FACA issues, or any other for that matter.

It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Would you connect with Ann Martin on the following:

b5

I will respond to Tara on the 2nd paragraph.

Thx

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, (b) (5) We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee (b) (5) get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. (b) (5)

(b) (5)

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6 >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that (b) (5) to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. (b) (5)

(b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:

(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

National Institutes of Health
Turning Discovery into Health

From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] <s b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

(b) (5)

b5 Thanks

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 3/1/2021 9:13:11 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Harris, Claire (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4b5754f95cf44f8a2655beda3899166-harriscl]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Claire got hold of me so we are all set. But thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Monday, March 1, 2021 4:13 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Do you want me to schedule something to start in a few minutes?

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Monday, March 1, 2021 3:14 PM
To: Harris, Claire (NIH/OD) [E] < b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E] b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I'm free right now.

From: Harris, Claire (NIH/OD) [E] b6
Sent: Monday, March 1, 2021 3:10 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi,

Just finished my meeting with Tara. Could we schedule a quick call this afternoon?

Thanks,

Claire

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Monday, March 1, 2021 9:43 AM
To: Harris, Claire (NIH/OD) [E] < b6 >
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Claire,
Can you let me know when you've met with Tara today and if there are any other tweaks to the summary? I've noted that OSP recommends the FNIH option. I don't know if you agree and/or want to note OFACP's view.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Monday, March 1, 2021 9:20 AM
To: Schwetz, Tara (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 ; Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Thanks, Tara. Michelle and I still think FNIH is the best option. I'll check with Claire on when you are meeting today in case there's anything else we should know before I send to LT and cc everyone.

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Sunday, February 28, 2021 12:26 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Harris, Claire (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Ellen,

This looks great. The only suggestion I have is to provide a recommended option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Friday, February 26, 2021 at 2:52 PM
To: Tara Schwetz < b6
Cc: "Culp, Michelle (NIH/OD) [E]" < b6 "Harris, Claire (NIH/OD) [E]" < b6 , "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Tara,

Claire, Patti, and Michelle and I have assembled these options and conferred with Ann Martin. I understand that you and Claire are scheduled to talk on Monday, so please let me know if you have further thoughts. I'm happy to transmit the document to Dr. Tabak (I'll copy everyone), since Michelle and I report to him on ACTIV issues. However I still haven't gotten any feedback from him on my earlier similar list of options, so I certainly welcome whatever you can do to bring this to his attention.

Thanks very much,
Ellen

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Harris, Claire (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: 3 b6 | **M:** 3 b6

From: "Gadbois, Ellen (NIH/OD) [E]" < b6
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz < b6 "Harris, Claire (NIH/OD) [E]" < b6 "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
Cc: "Culp, Michelle (NIH/OD) [E]" b6
Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Dear all,

I understand that you have been thinking further about some options that Claire, Patti, Michelle and I discussed last week regarding a potential committee to vet requests for use of biospecimens from the ACTIV trials. I wanted to let you know that I actually have not heard anything from Dr. Tabak on whether he wants NIH (or FNIH) to stand up such a committee. b5 I then wrote to Dr. Tabak last Thursday (see below) with potential options and a request for guidance, and re-upped the question yesterday afternoon, but haven't received a response. So I don't know if we should sort things out further without some guidance from Dr. Tabak. He's presumably heard this whole presentation from FNIH but I don't know how he reacted. (I'm going to write to David Wholley next and will let you know what he says.)

So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

Thanks,

Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi Larry,
I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

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Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

National Institutes of Health
Turning Discovery into Health

From: Wholley, David (FNIH) [T] < b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6 >
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
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b5 Thanks

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 3/1/2021 8:35:31 PM
To: Harris, Claire (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4b5754f95cf44f8a2655beda3899166-harriscl]
CC: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

OK

From: Harris, Claire (NIH/OD) [E] < b6
Sent: Monday, March 1, 2021 3:32 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Will Skype you now.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, March 1, 2021 3:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E] b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I'm free right now.

From: Harris, Claire (NIH/OD) [E] b6
Sent: Monday, March 1, 2021 3:10 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi,

Just finished my meeting with Tara. Could we schedule a quick call this afternoon?

Thanks,

Claire

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Monday, March 1, 2021 9:43 AM
To: Harris, Claire (NIH/OD) [E] < b6 >
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E]

b6

Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Claire,
Can you let me know when you've met with Tara today and if there are any other tweaks to the summary? I've noted that OSP recommends the FNIH option. I don't know if you agree and/or want to note OFACP's view.
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Sent: Monday, March 1, 2021 9:20 AM
To: Schwetz, Tara (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] [redacted], Harris, Claire (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Thanks, Tara. Michelle and I still think FNIH is the best option. I'll check with Claire on when you are meeting today in case there's anything else we should know before I send to LT and cc everyone.

From: Schwetz, Tara (NIH/OD) [E] < b6
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Cc: Culp, Michelle (NIH/OD) [E] [redacted], Harris, Claire (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Ellen,

This looks great. The only suggestion I have is to provide a recommended option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Friday, February 26, 2021 at 2:52 PM
To: Tara Schwetz b6
Cc: "Culp, Michelle (NIH/OD) [E]" < b6 "Harris, Claire (NIH/OD) [E]" b6 >, "Brandt Hansberger, Patricia (NIH/OD) [E]" b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Tara,

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gotten any feedback from him on my earlier similar list of options, so I certainly welcome whatever you can do to bring this to his attention.
Thanks very much,
Ellen

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Harris, Claire (NIH/OD) [E] b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b5

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Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
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Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz < b6 "Harris, Claire (NIH/OD) [E]" b6 "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
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So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

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Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

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I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

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Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

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Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

OK. I'll wait to send the email to LT until after you meet. Thanks for your ongoing guidance!
Ellen

From: Harris, Claire (NIH/OD) [E] < b6
Sent: Monday, March 1, 2021 10:02 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Ellen,

Sure. My meeting is from 2:30pm-3:15pm. Will touch base with you after. OFACP agrees with OSP as FNIH being the best option.

Thanks,

Claire

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Monday, March 1, 2021 9:43 AM
To: Harris, Claire (NIH/OD) [E] < b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] b6
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OD TALKBACK
Connect While Stopping the Spread

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Date: Friday, February 26, 2021 at 2:52 PM
To: Tara Schwetz < b6
Cc: "Culp, Michelle (NIH/OD) [E]" b6 "Harris, Claire (NIH/OD) [E]" b6 >, "Brandt Hansberger, Patricia (NIH/OD) [E]" b6
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NIH National Institutes of Health
Turning Discovery into Health

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Sent: 3/1/2021 3:12:18 PM
To: Berger, Adam (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfbf537ab62640ffa150a8f65241879f-bergerac]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Yes, that would be a good setting.

From: Berger, Adam (NIH/OD) [E] <b6
Sent: Monday, March 1, 2021 10:07 AM
To: Gadbois, Ellen (NIH/OD) [E] <b6
Cc: Culp, Michelle (NIH/OD) [E] <b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Sounds like it could be an informative lunch bunch to have a general overview of FACA and how NIH has applied it

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
b6 | b6

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, March 1, 2021 10:01 AM
To: Berger, Adam (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Nope. Michelle and I are hoping that FNIH can be persuaded to do this, since we think it would be an easy fit with what they are already doing. But if it winds up with NIH, we may need to dig more into details like this & will share what we find out. Also I bet that Ann would be willing to talk more in a general sense to OSP about these types of committees in the interest of ongoing education...

From: Berger, Adam (NIH/OD) [E] b6
Sent: Monday, March 1, 2021 9:57 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Interesting. So did she indicate how they calculate that risk? Is it based on the number of individuals in a meeting for instance?

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy

Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
b6 | b6

National Institutes of Health
Turning Discovery into Health

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 6:08 PM
To: Berger, Adam (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I think Ann used the phrase "collective discussions" when we spoke to her yesterday, but basically it's on a scale of relative risk to NIH.

Sent from my iPhone

On Feb 26, 2021, at 5:13 PM, Berger, Adam (NIH/OD) [E] b6 > wrote:

Thanks. Good coverage of the options. One question on the following:

Committee convened by NIH including external members, giving individual views to NIH	No	NIH selects members, manages ABPC activities. Committee members do not seek consensus but provide individual views to NIH. NIH makes decision about disposition of biospecimens.	**Pros**: -Could be set up fairly quickly -Can meet as often as needed **Cons**: -Lack of ability to have collective discussions may make opinions less informed

My understanding of FACA is that you can have collective discussions. It is just that they cannot provide a consensus opinion. This part thus isn't as clear to me: "Lack of ability to have collective discussions may make opinions less informed". Is my understanding incorrect?

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
b6 | b6

<image002.png>

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 3:04 PM
To: Berger, Adam (NIH/OD) [E] b6

Cc: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Adam,
FYI: here is the document Ellen, Patti Brandt and I put together outlining options for groups that are FACA and non-FACA committees. This may be useful for other situations.
-Michelle

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To: Schwetz, Tara (NIH/OD) [E] b6 >
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b5

Best,

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Associate Deputy Director, NIH
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<image003.png>

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Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

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Happy to chat further.

Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

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Sent: Thursday, February 18, 2021 5:12 PM
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Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

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(b) (5)

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(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

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Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

<image004.png>

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to

make these decisions. (b) (5)

(b) (5)

b5 Thanks

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 3/1/2021 12:35:30 AM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Fwd: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Do you still think we should recommend FNIH?

Sent from my iPhone

Begin forwarded message:

From: "Schwetz, Tara (NIH/OD) [E]" < b6
Date: February 28, 2021 at 12:26:20 AM EST
To: "Gadbois, Ellen (NIH/OD) [E]" < b6
Cc: "Culp, Michelle (NIH/OD) [E]" < b6 "Harris, Claire (NIH/OD) [E]" < b6 "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Ellen,

This looks great. The only suggestion I have is to provide a recommended option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Gadbois, Ellen (NIH/OD) [E]" < b6
Date: Friday, February 26, 2021 at 2:52 PM
To: Tara Schwetz < b6
Cc: "Culp, Michelle (NIH/OD) [E]" < b6 "Harris, Claire (NIH/OD) [E]" < b6 "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

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Thanks very much,
Ellen

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz b6 "Harris, Claire (NIH/OD) [E]" b6 >, "Brandt Hansberger, Patricia (NIH/OD) [E]" <b b6
Cc: "Culp, Michelle (NIH/OD) [E]" b6
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Happy to chat further.

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Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] < b6
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Sent: 2/26/2021 8:01:23 PM
To: Jessica (NIH/OD) Tucker [E] b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options
Attachments: ACTIV ABPC options 26 Feb 2021.docx

FYI Jessica. And we have learned more about DSMBs, which I can tell you about when you are free.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Friday, February 26, 2021 2:53 PM
To: Schwetz, Tara (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
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b5
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National Institutes of Health
Turning Discovery into Health

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To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
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Sent: 2/26/2021 8:00:18 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Sure.

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 2:59 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen,
Thanks for cleaning this up and sending to Tara.
This has turned out to be an interesting document that could be a useful guide to others in OSP, such as the gene-drive group who are thinking about assembling a committee. Should we share it with our respective supervisors, Jessica & Adam?

-Michelle

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 2:17 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK—here is a clean version. Claire, can you remind Tara that Michelle and I are reporting to Dr. Tabak on ACTIV issues and tell her that FNIH asked the two of us to look at whether there were problems with their proposal? From the earlier emails, I couldn't tell if she knows & I don't want to get wires crossed.
Thanks,
Ellen

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 1:45 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi—Claire and I reviewed and just a few further edits (mostly spacing and taking periods out of third column for consistency-or you can have all periods). Also, I can't believe I didn't remember that if the FACA bill is enacted, we can say goodbye to workgroups as well. So, I made a note in that column.

Per your Q below, Claire asked to send to Tara first and cc all of us.

Thanks so much!

Patti

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 1:01 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 ; Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks Patti & Claire. I accepted the existing edits and made a few modifications for formatting. I also changed "grantees" to "awardees" in a few places for consistency. Those changes are all in redline still.

Patti—re. your question about using ACD/CoC for this sort of thing—I think they already went down that road with the HeLa WG for the ACD, so I didn't put in that angle as a con.

I'll clean this up next and send around the clean one. You all should let me know if you see any remaining issues.

Claire—do you think Tara wants to see this before it goes to LT? I am happy to send it to LT if you think it can go now (or after meeting with Tara Monday) and I would cc Tara & all of you folks...

Thanks again,
Ellen

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 12:10 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 Harris, Claire (NIH/OD) [E] < b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-I am ccing Claire since we are on the home stretch (I hope!) of finishing this up.

I spoke to Claire and added some minor edits and notations. I added a couple of "cons" but I don't know if they really qualify.

Claire is fine if you send the pro/con document and cc everyone as you most familiar with the ACTIV FNIH activities, know the players, have the background, etc.

If you have a sense of when you think you'd be done, that would be great. Claire has her standing meeting on Monday with Tara.

Please let us know if you have any Qs or need clarity on anything!

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 11:40 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I would choose the ACD because they are used to dealing with data access requests coming through the ACD HeLa Working Group.

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 10:58 AM

To: Culp, Michelle (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes – Just got out of one meeting with Claire and headed into another. I showed her the document and she wanted your opinion of which committee would make more sense for this work group, the ACD or the CoC. Knowing a working group concept isn't optimal, she still wanted to get your thoughts. I will have a couple of edits to the work group row based on my discussion with Claire.

P

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 10:21 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen,
I reviewed your edits to the document. Thanks for adding the "as proposed by FNIH" to the section headers and for clarifying text in the table. Much better!

Patti,
If your hand is on the document now, I think you can remove the 2nd column since Ellen made it better as the 1st column.

Thank you!
-Michelle

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 9:37 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ah – you beat me. I'll add to your edits.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 9:36 AM
To: Culp, Michelle (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks very much, Michelle. I made some proposed edits.

Note that I'm suggesting we delete what was formerly the first column and replace with something a little more comprehensive.

One key thing based on my understand of our PPP structures & FNIH steering committees—FNIH/the ACTIV Steering Committees can't actually advise NIH—the Steering Committee can only advise the grantees. (Somehow it works out.) And as long as the ACTIV Steering Committee only advises grantees, it seems like grantees would make the final decision of who gets what, so there's an out here if the grantee doesn't want to follow the ACTIV advice and/or for NIH to get involved.

Finally, b5
b5

From: Culp, Michelle (NIH/OD) [E] b6 >
Sent: Thursday, February 25, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,
I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 ; Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

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Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Martin, Ann (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] < b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

From: Martin, Ann (NIH/OD) [E] < b6
Sent: Thursday, February 25, 2021 9:10 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 ; Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
2:30 works best for me today, if that still works on your end.

For your consideration in the meantime, (b) (5) We are not aware of committees that fall into that "operational" category in the absence of a statutory basis for such a role. It is hard for me to see "operational" as an option for the biospecimen committee. It is correct that the sharing of information in a group setting between federal officials and experts does not implicate FACA. The important aspect in such a scenario,

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Bethesda, MD 20892
b6 (main)
b6

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Cc: Gadbois, Ellen (NIH/OD) [E] <b6>; Culp, Michelle (NIH/OD) [E] b6>; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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- 9:00
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Would you connect with Ann Martin on the following:

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Cc: Culp, Michelle (NIH/OD) [E] b6
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Dear Larry,

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Thanks,
Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

National Institutes of Health
Turning Discovery into Health

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] < b6 >
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)
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b5 Thanks

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Sent: 2/26/2021 3:05:53 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I should add that I meant to write that I don't think we want 2 committees, as FNIH proposed. Seems like overkill. But that's just my opinion.

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 9:37 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ah – you beat me. I'll add to your edits.

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Friday, February 26, 2021 9:36 AM
To: Culp, Michelle (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks very much, Michelle. I made some proposed edits.

Note that I'm suggesting we delete what was formerly the first column and replace with something a little more comprehensive.

One key thing based on my understand of our PPP structures & FNIH steering committees—FNIH/the ACTIV Steering Committees can't actually advise NIH—the Steering Committee can only advise the grantees. (Somehow it works out.) And as long as the ACTIV Steering Committee only advises grantees, it seems like grantees would make the final decision of who gets what, so there's an out here if the grantee doesn't want to follow the ACTIV advice and/or for NIH to get involved.

Finally, b5
b5

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Thursday, February 25, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,
I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 ; Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Martin, Ann (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 v>
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

From: Martin, Ann (NIH/OD) [E] b6
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Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E] < b6
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It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Would you connect with Ann Martin on the following:

b5

I will respond to Tara on the 2nd paragraph.

Thx

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] b6 >
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, (b) (5) We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH

A: Building 1, Room 138
P: 301-402-3965 | M: 301-538-4920

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz < b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee (b) (5)

, get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it (b) (5)

(b) (5)

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM

To: Tara Schwetz [b6] >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] < [b6]
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] [b6] >
Cc: Culp, Michelle (NIH/OD) [E] < [b6]
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Culp, Michelle (NIH/OD) [E] [b6]
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

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(b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:
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In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,

Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/25/2021 12:10:30 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I'm free except 1-2 and after 3:30. Thanks

Sent from my iPhone

On Feb 24, 2021, at 6:13 PM, Brandt Hansberger, Patricia (NIH/OD) [E] < b6 wrote:

That's fine with me. I can reach out to Ann and check on her availability. What does your schedule look like tomorrow?

P

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 6:12 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I think that is OK (pretty much what I was thinking). I can wordsmith a little tomorrow morning. I am wondering if we should talk to OGC now. I want to understand how it is that DSMBs work anyway.

Sent from my iPhone

On Feb 24, 2021, at 6:05 PM, Brandt Hansberger, Patricia (NIH/OD) [E] < b6 > wrote:

What do you think about this model? Claire is OK with it, and if you are we can work together on the wording. I basically just threw this together to give you an idea. But it does fit on one screen 😊

FACA Options:

(b) (5)

Non-FACA Options:

(b) (5)

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 ; Harris, Claire (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH

A: Building 1, Room 138
P: b6 | M: b6

<image001.png>

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz b6 >, "Harris, Claire (NIH/OD) [E]" b6 , "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
Cc: "Culp, Michelle (NIH/OD) [E]" b6
Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Dear all,

I understand that you have been thinking further about some options that Claire, Patti, Michelle and I discussed last week regarding a potential committee to vet requests for use of biospecimens from the ACTIV trials. I wanted to let you know that I actually have not heard anything from Dr. Tabak on whether he wants NIH (or FNIH) to stand up such a committee. b5 I then wrote to Dr. Tabak last Thursday (see below) with potential options and a request for guidance, and re-upped the question yesterday afternoon, but haven't received a response. So I don't know if we should sort things out further without some guidance from Dr. Tabak. He's presumably heard this whole presentation from FNIH but I don't know how he reacted. (I'm going to write to David Wholley next and will let you know what he says.)

So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi Larry,
I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

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(b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:
(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

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Sent: 2/24/2021 3:23:40 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

My last meeting ran late—trying to join now

Sent from my iPhone

On Feb 24, 2021, at 10:03 AM, Culp, Michelle (NIH/OD) [E] < b6 wrote:

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 10:03 AM
To: Culp, Michelle (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi – I sent you an invite for 10:15.

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 9:06 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I'm free after 10am.

Patti, scroll to the bottom to see the email Ellen sent to Larry on Feb 18.
-Michelle .

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 8:56 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I'm tied up until 10 a.m. and should read through all this but then I'm free. Do we know if Tara has connected with Dr. Tabak on this?

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 8:54 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E]

b6 >
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good morning. Do you have time to connect this morning? I have a 11:00 – 11:30 meeting and then something 2:00 – 3:00, but my preference is to connect this morning since Claire would like to see if we could get something to Tara today.

Can we discuss how you would like to proceed putting together an options document for leadership. I am very flexible. Also, Claire wants me to get your thoughts in particular whether CoC is a good fit. She thinks the ACD would work as well but liked your input on the CoC. The charters are attached.

From: Harris, Claire (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:05 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Please see below. Please connect with Ellen and let her know of the 2 options and ask her if she wants to put together the summarizing document or if she wants us to start something and send to her to update, etc? Probably should get the document to Tara later today.

Thx

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 1:07 AM
To: Harris, Claire (NIH/OD) [E] b6 >
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Great. Are you pulling together a document summarizing the options? Or are Ellen and Michelle?

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: **b6** | **M:** **b6**

<image001.png>

From: "Harris, Claire (NIH/OD) [E]" < **b6**
Date: Tuesday, February 23, 2021 at 8:53 AM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

The working group option will work as well. Copying my comments from below: We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

In summary, I'm fine if the working group is needed for more than 1 year with a max of 2 years.

We will need to decide where Activ could fit. (b) (5)

(b) (5)

In summary, we have a non-FACA and FACA option to provide to FC.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Tuesday, February 23, 2021 2:22 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Claire,

Thanks – this does seem like a viable option.

What about the option to have a working group of a parent FACA committee? From my perspective (and from what I understand the intention to be), I think it would be fine if its membership was time-limited and only lasted 1-2 years. Is that not feasible? I want to ensure we lay out all of the potential options, with a recommendation as to which we think would best align with the goals of forming a committee/group and with FACA.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Monday, February 22, 2021 at 2:11 PM
To: Tara Schwetz b6 >
Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

Patti and I discussed your approach with Ann regarding an internal NIH committee with outside consultants providing individual perspectives. She thought it sounded fine with some reminders. As the committee would be comprised solely of Federal members, be mindful of communications with outside experts, e.g., when setting up a meeting, emails should be separate from the main committee; if two people with individual perspectives are invited to a meeting, send separate emails to avoid generating outside discussion. Ann also noted the importance of emphasizing that these individuals are consultants advising the committee, so be sure to have a record that the committee is asking for individual perspectives. In addition, she mentioned being mindful of implications under FOIA; however, it wasn't so much of a concern since this is an NIH committee with Federal members deliberating and providing recommendations that another official could act on. She added that the agency would have the argument that the consultants were hired by NIH to provide expertise to the committee.

So, this is a viable option for consideration by leadership. Wasn't sure if you wanted me to touch base with Ellen? Or wait until you had a chance to talk with LAT and make final decisions?

Best,

Claire

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 12:48 PM
To: Schwetz, Tara (NIH/OD) [E] < **b6**
Cc: Harris, Claire (NIH/OD) [E] < **b6**
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ok. Will connect with Ann.

Maybe some confusion re: subcommittees vs. WGs. We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

Subcommittees are a bit different and more formal. Here is the standard language from charters:

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Also, subcommittees follow most FACA rules, i.e. open to the public, meetings announced in FRN, minutes, etc.

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] < b6 >
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, (b) (5) We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

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Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

<image003.png>

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Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

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(b) (5)

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

<image004.png>

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz < b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) | b6
Cc: Culp, Michelle (NIH/OD) [E]
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Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: **b6**
fax: **b6**

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) b6
Cc: Adam, Stacey (FNIH) [T] <

Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

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Sent: 2/18/2021 6:14:11 PM
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Subject: RE: biospecimen prioritization committee--how could we implement?

Thanks very much. Good to talk to you and Claire.
Ellen

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 1:01 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: biospecimen prioritization committee--how could we implement?

FYI:

- NIA: https://agingresearchbiobank.nia.nih.gov/faq/#faq-8 Biobank Scientific Review Committee (BSRC)
- NICHD: https://dash.nichd.nih.gov/resource/FAQs NICHD DASH Data or Biospecimen Access Committee
- NHLBI: https://biolincc.nhlbi.nih.gov/media/guidelines/handbook.pdf?link_time=2021-02-18_12:17:21.777498
- NCI: https://www.cancer.gov/research/infrastructure/clinical-trials/nctn

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Wednesday, February 17, 2021 4:59 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: biospecimen prioritization committee--how could we implement?

Hi Patti,
Thanks for the quick chat this afternoon. Here's the issue in a nutshell:

Cliff Lane wants to establish a biospecimen prioritization committee to handle requests to use biospecimens collected in the ACTIV trials. David Wholly at FNIH sent Michelle the attached slides describing the plan and a message below. FNIH does not want to run this—they expect NIH to implement. However, (b) (5)
(b) (5)

So here are the other paths I'm thinking about:
(b) (5)

(b) (5)

Any ideas you and/or Claire have are welcome. Happy to get on the phone again.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6 v>
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/18/2021 4:47:43 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: biospecimen prioritization committee--how could we implement?

OK

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 11:44 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Ellen,
No worries. I've been on calls all morning. Talk to you at 12:30!

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 11:32 AM
To: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Sorry I didn't reply to you earlier. I'm happy to talk to just you prior to the 12:30 with Patti & Claire. If you are free go ahead and Skype call, although I'm going to grab lunch at some point this hour.

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:12 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Patti,
Thanks for the attachments. They are really helpful!

Ellen,
Let me know if you want to chat about this information.
-Michelle

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 8:57 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Good morning – I am looking through the files on OFACP's shared drive and found the attached which mentions DSMBs, which may be helpful. Also, FYI, see 2nd attachment which lists activities not covered by FACA and slides 22 and 23 from the third attachment which was from a PO training from last May that Claire participated in.

In any event, these options look like you are on the right track to me and I'm sure Claire will have other thoughts.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 4:59 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: biospecimen prioritization committee--how could we implement?

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/18/2021 3:43:25 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: your thoughts on biospecimen prioritization committee idea?

I'm talking to committee management today about what makes an activity FACA or not FACA, so should have more thoughts to share soon.

From: Adam, Stacey (FNIH) [T] < **b6**
Sent: Thursday, February 18, 2021 10:37 AM
To: Read, Sarah (NIH/NIAID) [E] < **b6** Gadbois, Ellen (NIH/OD) [E] < **b6**
Cc: Culp, Michelle (NIH/OD) [E] < **b6**
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi Sarah,

That was my concern is that TOC doesn't have industry either and would be duplicative of the Oversight committee of NIHers proposed.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: **b6** | Mobile: b6

From: Read, Sarah (NIH/NIAID) [E] < **b6**
Sent: Thursday, February 18, 2021 8:29 AM
To: Adam, Stacey (FNIH) [T] b6 Gadbois, Ellen (NIH/OD) [E] < **b6**
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Stacey, I'm not really sure what I was thinking...and in fact, can't really think of a way to use the committee as a go-between since they are largely NIHers.

From: Adam, Stacey (FNIH) [T] < **b6**
Sent: Wednesday, February 17, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi All,

Thanks for keeping me in the loop.

Sarah, not sure on the TOC. Did you have a notion to have it replace the oversight committee or something else?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 | Mobile: b6

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, February 17, 2021 4:50 PM
To: Read, Sarah (NIH/NIAID) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 Adam, Stacey (FNIH) [T] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Thanks, Sarah. FYI NIH has working groups of FACA committees that develop "findings" or do "analysis" and/or collect individual views, but a formal consensus recommendation to NIH only comes from a FACA Committee. BUT there is probably a way for a group to advise the investigators themselves (not NIH), which is essentially how the partnerships work where the steering committees can provide direction to investigators. Anyway, I am trying to get more information/ideas on a few ideas. I was just hoping there was some existing structure we could use. Interestingly DSMBs are not FACA committees.

From: Read, Sarah (NIH/NIAID) [E] b6
Sent: Wednesday, February 17, 2021 2:41 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 Adam, Stacey (FNIH) [T] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi Ellen,
Thank you for your thoughts on this committee and for pointing out possible pitfalls. I'm cutting and pasting your questions below with my answers alongside:

(b) (5)

I'm copying Stacey to for her awareness and input if she has any ideas. Stacey, I'm wondering if there might be a role for the Trial Oversight Committee in this somehow?

I'm also happy to get on a call if that would be easier but am pretty booked today and tomorrow...I do have time on Friday.

Thanks,
Sarah

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: your thoughts on biospecimen prioritization committee idea?

Oops—resending because I had meant to cc Michelle.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] b6
Subject: your thoughts on biospecimen prioritization committee idea?

Dear Sarah,

Michelle and I understand from David Wholley that Cliff Lane wants to establish a (b) (5) David sent Michelle the attached slides describing the plan and a message below. I know the general plan has also been discussed in the ACTIV therapeutics working group.

(b) (5)

Happy to get on the phone if this is easier to discuss, or let me know if I should contact someone else at NIAID.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

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Sent: 2/18/2021 3:12:40 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: biospecimen prioritization committee--how could we implement?

Thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] <b6
Sent: Thursday, February 18, 2021 10:12 AM
To: Gadbois, Ellen (NIH/OD) [E] <b6
Cc: Culp, Michelle (NIH/OD) [E] <b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Hi-I just spoke to Claire and 12:30 works (she has an 11:00).

I'll send around a WebEx Invite in case we need to share screens.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 10:05 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Patti should we try for 11 a.m.? I call send around a conference call #.

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:42 AM
To: Gadbois, Ellen (NIH/OD) [E] <b6 Brandt Hansberger, Patricia (NIH/OD) [E] <b6 .gov>
Subject: RE: biospecimen prioritization committee--how could we implement?

I'm free 11:00-1:00.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:38 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <b6 Culp, Michelle (NIH/OD) [E] <b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Right now I'm free anytime except 1-3. Michelle do you have time to join?
Thanks so much

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:27 AM

To: Culp, Michelle (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Hi-just heard from Claire that any time today is fine. What works for you?

P

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:12 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 Gadbois, Ellen (NIH/OD) [E]
b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Patti,
Thanks for the attachments. They are really helpful!

Ellen,
Let me know if you want to chat about this information.
-Michelle

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Cc: Culp, Michelle (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E]
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Good morning – I am looking through the files on OFACP's shared drive and found the attached which mentions DSMBs, which may be helpful. Also, FYI, see 2nd attachment which lists activities not covered by FACA and slides 22 and 23 from the third attachment which was from a PO training from last May that Claire participated in.

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Cliff Lane wants to establish a biospecimen prioritization committee to handle requests to use biospecimens collected in the ACTIV trials. David Wholly at FNIH sent Michelle the attached slides describing the plan and a message below. FNIH does not want to run this—they expect NIH to implement. However, (b) (5)
presumably need to go through a federal advisory committee per FACA. We don't want to have to establish a new FACA.

So here are the other paths I'm thinking about:

(b) (5)

Any ideas you and/or Claire have are welcome. Happy to get on the phone again.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
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Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/17/2021 3:30:10 PM
To: Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: your thoughts on biospecimen prioritization committee idea?
Attachments: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Oops—resending because I had meant to cc Michelle.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] < b6
Subject: your thoughts on biospecimen prioritization committee idea?

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(b) (5)

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Sent: 2/16/2021 4:09:37 PM
To: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Subject: RE: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Maybe we should chat quickly if you have time. (b) (5)

I don't see why the biospecimen committee can't just be attached to the existing ACTIV clinical trial infrastructure somehow with some central management at NIH—I just don't understand the infrastructure well enough to come up by myself with a plan. Maybe we could talk and try to sketch it out and come up with a proposal.

And if NIH does run this, we should check with the current FACA person. I think Jenny Spaeth has b6, so I'll find out who the new person is. (This is an NIH implementation problem, not an FNIH problem, so David can't tell us whether or not to consult our lawyers!)

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Thursday, February 11, 2021 11:35 PM
To: Wholley, David (FNIH) [T] < b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: RE: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

David,
I am not a FACA expert but I understand your concern. In my read of the slides you provided, the committee includes feds, academics and industry experts. (b) (5)

Some other thoughts: (b) (5)

Let me know if I should find a FACA expert to weigh in on this. I am taking leave tomorrow, but will check email periodically.
Best,
Michelle

From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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b5

b5 Thanks

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Sent: 3/1/2021 1:44:57 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

That's still my preference. They would have the most flexibility in who participates, when, and how information is shared.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Sunday, February 28, 2021 7:36 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Subject: Fwd: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Do you still think we should recommend FNIH?

Sent from my iPhone

Begin forwarded message:

> **From:** "Schwetz, Tara (NIH/OD) [E]" < b6
> **Date:** February 28, 2021 at 12:26:20 AM EST
> **To:** "Gadbois, Ellen (NIH/OD) [E]" b6
> **Cc:** "Culp, Michelle (NIH/OD) [E]" b6 "Harris, Claire (NIH/OD) [E]" b6 . "Brandt Hansberger, Patricia (NIH/OD) [E]" < b6
> **Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options**
>
> Ellen,
>
> This looks great. The only suggestion I have is to provide a recommended option.
>
> Best,
>
> **Tara A. Schwetz, PhD**
> Associate Deputy Director, NIH
> **A:** Building 1, Room 138
> **P:** b6 | **M:** b6
>
> 
>
>
> ---
>
> **From:** "Gadbois, Ellen (NIH/OD) [E]" < b6
> **Date:** Friday, February 26, 2021 at 2:52 PM
> **To:** Tara Schwetz b6 >
> **Cc:** "Culp, Michelle (NIH/OD) [E]" < b6 "Harris, Claire (NIH/OD) [E]" b6 . "Brandt Hansberger, Patricia (NIH/OD) [E]" b6
> **Subject:** RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options
>
> Hi Tara,

Claire, Patti, and Michelle and I have assembled these options and conferred with Ann Martin. I understand that you and Claire are scheduled to talk on Monday, so please let me know if you have further thoughts. I'm happy to transmit the document to Dr. Tabak (I'll copy everyone), since Michelle and I report to him on ACTIV issues. However I still haven't gotten any feedback from him on my earlier similar list of options, so I certainly welcome whatever you can do to bring this to his attention.
Thanks very much,
Ellen

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Harris, Claire (NIH/OD) [E] <ha b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

(b) (5)
(b) (5) Thanks for flagging this.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Gadbois, Ellen (NIH/OD) [E]" < b6 >
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz b6 , "Harris, Claire (NIH/OD) [E]" b6 , "Brandt Hansberger, Patricia (NIH/OD) [E]" b6
Cc: "Culp, Michelle (NIH/OD) [E]" b6 >
Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Dear all,

I understand that you have been thinking further about some options that Claire, Patti, Michelle and I discussed last week regarding a potential committee to vet requests for use of biospecimens from the ACTIV trials. I wanted to let you know that I actually have not heard anything from Dr. Tabak on whether he wants NIH (or FNIH) to stand up such a committee. b5

I then wrote to Dr. Tabak last Thursday (see below) with potential options and a request for guidance, and re-upped the question yesterday afternoon, but haven't received a response. So I don't know if we should sort things out further without some guidance from Dr. Tabak. He's presumably heard this whole presentation from FNIH but I don't know how he reacted. (I'm going to write to David Wholley next and will let you know what he says.)

So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of

the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi Larry,
I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that (b) (5) to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. (b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:
(b) (5)

(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Berger, Adam (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CFBF537AB62640FFA150A8F65241879F-BERGERAC]
Sent: 2/26/2021 10:41:45 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Below is from GSA which oversees FACA. I interpret this to indicate that you can have meetings where multiple individuals are brought together to provide their own advice as long as they are not forming a consensus opinion. Of course, I don't interpret FACA for NIH so perhaps that is not the way we have done so (though I would really question it if we did view it otherwise).

https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/advice-and-guidance/when-is-federal-advisory-committee-act-faca-applicable

SCENARIO ONE - FACA NOT APPLICABLE

Factual assumptions: As part of continuing National Performance Review (NPR) initiatives, the Administrator wishes a series of meetings with senior corporate executives from companies which have faced or are facing challenges similar to those facing government today, e.g., downsizing, restructuring, reduced resources, creative financing needs, labor and human resources concerns, increased customer relations demands, etc.

The Administrator's intent is to obtain experiential and anecdotal information from each executive on challenges faced by his/her company, how the company met the challenges, approaches which were productive or successful, and those which were not. The attendees may or may not change from session to session. The specific agenda subjects will likely change and may be set in advance or be free form. No collective advice or recommendations resulting from group deliberation or interaction is expected or will be solicited.

FACA does not apply because:

- The intent is to obtain information or viewpoints from individual attendees as opposed to advice, opinions or recommendations from the group acting in a collective mode.

FACA coverage could become an issue if:

- The function/mission of the group changes over time and the Administrator begins to use the group as a source of collective advice or recommendations. The more static the group composition, i.e., the same attendees at each meeting, the more likely an issue of FACA's applicability will arise.

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
b6 | b6

National Institutes of Health
Turning Discovery into Health

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 5:25 PM
To: Berger, Adam (NIH/OD) [E] < b6
Cc: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I'm not sure. To clarify, we'd have to go back to Claire Harris and Patti Brandt to see if the non-FACA group would be restricted on collective *discussion* as well as collective *decision*.

From: Berger, Adam (NIH/OD) [E] < b6 >
Sent: Friday, February 26, 2021 5:14 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 v>
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Thanks. Good coverage of the options. One question on the following:

Committee convened by NIH including external members, giving individual views to NIH	No	NIH selects members, manages ABPC activities. Committee members do not seek consensus but provide individual views to NIH. NIH makes decision about disposition of biospecimens.	**Pros**: -Could be set up fairly quickly -Can meet as often as needed **Cons**: -Lack of ability to have collective discussions may make opinions less informed

My understanding of FACA is that you can have collective discussions. It is just that they cannot provide a consensus opinion. This part thus isn't as clear to me: "Lack of ability to have collective discussions may make opinions less informed". Is my understanding incorrect?

Adam C. Berger, PhD
Director, Division of Clinical and Healthcare Research Policy
Office of Science Policy
Office of the Director | National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
b6 v | b6

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Turning Discovery into Health

From: Culp, Michelle (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 3:04 PM
To: Berger, Adam (NIH/OD) [E] < b6
Cc: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Adam,

FYI: here is the document Ellen, Patti Brandt and I put together outlining options for groups that are FACA and non-FACA committees. This may be useful for other situations.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Friday, February 26, 2021 2:53 PM
To: Schwetz, Tara (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Harris, Claire (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Hi Tara,

Claire, Patti, and Michelle and I have assembled these options and conferred with Ann Martin. I understand that you and Claire are scheduled to talk on Monday, so please let me know if you have further thoughts. I'm happy to transmit the document to Dr. Tabak (I'll copy everyone), since Michelle and I report to him on ACTIV issues. However I still haven't gotten any feedback from him on my earlier similar list of options, so I certainly welcome whatever you can do to bring this to his attention.
Thanks very much,
Ellen

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 >; Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Gadbois, Ellen (NIH/OD) [E]" b6 >
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz < b6 "Harris, Claire (NIH/OD) [E]" b6 >, "Brandt Hansberger, Patricia (NIH/OD) [E]" b6 >
Cc: "Culp, Michelle (NIH/OD) [E]" b6
Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Dear all,

I understand that you have been thinking further about some options that Claire, Patti, Michelle and I discussed last week regarding a potential committee to vet requests for use of biospecimens from the ACTIV trials. I wanted to let you

know that I actually have not heard anything from Dr. Tabak on whether he wants NIH (or FNIH) to stand up such a committee. b5 I then wrote to Dr. Tabak last Thursday (see below) with potential options and a request for guidance, and re-upped the question yesterday afternoon, but haven't received a response. So I don't know if we should sort things out further without some guidance from Dr. Tabak. He's presumably heard this whole presentation from FNIH but I don't know how he reacted. (I'm going to write to David Wholley next and will let you know what he says.)

So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi Larry,
I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

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b5

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Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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b5

b5 Thanks

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Sent: 2/26/2021 1:51:04 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

There's no number in the Skype for you – what's the best # for me to call?

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 8:49 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK ready now

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 8:37 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK – just email me when you are ready

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 8:36 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 />
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I just got off a call so need about 5 minutes to review, but then yes

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 26, 2021 8:35 AM
To: Gadbois, Ellen (NIH/OD) [E] b >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Are you available for a quick skype?

From: Culp, Michelle (NIH/OD) [E] b6 >
Sent: Thursday, February 25, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,
I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 ; Martin, Ann (NIH/OD) [E] b6 v>
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 Martin, Ann (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

From: Martin, Ann (NIH/OD) [E] b6 >
Sent: Thursday, February 25, 2021 9:10 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
2:30 works best for me today, if that still works on your end.

For your consideration in the meantime, b5 We are not aware of committees that fall into that "operational" category in the absence of a statutory basis for such a role. It is hard for me to see "operational" as an option for the biospecimen committee. It is correct that the sharing of information in a group setting between federal officials and experts does not implicate FACA. The important aspect in such a scenario, however, is that it be grounded on an exchange of information. The non-government participants would not have an advisory role. This is different than an "operational" committee within the meaning of "operational" for purposes of the FACA regulations. It doesn't seem that the "information exchange" setting will suit NIH's/ACTIV's needs here, but I would be happy to explore this further with you.

I have also made a few notes below in red.

Happy to discuss this afternoon.

Thanks,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 7:55 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 >; Culp, Michelle (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Ann! Tara and Larry want us to lay out all the options in one email which I am working on with Ellen and she would like to have one more chat and wants to understand more how DSMB's work in particular. I took a crack at starting something (see directly below) and Ellen is going to start wordsmithing this tomorrow. Our goal is to keep this as concise as possible.

I know this is short notice, but wondering if you were available any of the times below tomorrow?

- 9:00
- Noon
- 2:30

FACA Options:

(b) (5)

Non-FACA Options:

(b) (5)

From: Martin, Ann (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 3:55 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
Thanks for the info below. I would be glad to talk with you and Claire about this on Monday. Would 11:30 or later work ok?
Hope you are doing well!
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6 .

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 2:07 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good afternoon. I am working with Claire on an ACTIV issue. Per the email trail below, b4 b4 b4 b4 The committee would be comprised of ACTIV trial team members, academic, and industry representatives who would set review and prioritization criteria, assess biospecimen requests, and recommend which ones should be reviewed by an oversight committee (see slide 6). Claire and I had a conversation with Ellen Gadbois and Michelle Culp yesterday about possible options if NIH were to form such a committee. The email Ellen sent to LAT below is based on that conversation.

The email exchange contains several ideas and Claire wanted your thoughts on the following idea from Tara:

(b) (5)

I just had a chat with Claire, and this wouldn't be a subcommittee or a workgroup of a full committee; it seems like something different. Claire wants to know if Tara's idea raised any FACA issues, or any other for that matter.

It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Harris, Claire (NIH/OD) [E] < b6 >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Would you connect with Ann Martin on the following:

b5

I will respond to Tara on the 2nd paragraph.

Thx

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, b5 We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6 >
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee b5 b5 b5, get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. b5 b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM

To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

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In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

NIH National Institutes of Health
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From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
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Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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b5

b5 Thanks

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To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
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OK -

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Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,
I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >; Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

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Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] b6 ; Martin, Ann (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] b6 ; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

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To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] b6 Culp, Michelle (NIH/OD) [E] < **b6**
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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2:30 works best for me today, if that still works on your end.

For your consideration in the meantime, b5
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I have also made a few notes below in red.

Happy to discuss this afternoon.

Thanks,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
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31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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Hi, Ann! Tara and Larry want us to lay out all the options in one email which I am working on with Ellen and she would like to have one more chat and wants to understand more how DSMB's work in particular. I took a crack at starting something (see directly below) and Ellen is going to start wordsmithing this tomorrow. Our goal is to keep this as concise as possible.

I know this is short notice, but wondering if you were available any of the times below tomorrow?

- 9:00
- Noon
- 2:30

FACA Options:

(b) (5)

Non-FACA Options:

(b) (5)

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Hi, Patti,
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Hope you are doing well!
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Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
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The email exchange contains several ideas and Claire wanted your thoughts on the following idea from Tara:

b5

I just had a chat with Claire, and this wouldn't be a subcommittee or a workgroup of a full committee; it seems like something different. Claire wants to know if Tara's idea raised any FACA issues, or any other for that matter.

It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 >
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Would you connect with Ann Martin on the following:

b5

I will respond to Tara on the 2nd paragraph.

Thx

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, b5 We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee b5
b5
b5 get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. b5
b5

Best,

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Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6 >
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM

To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that b5 to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. b5

b5

We briefly explored other non-FACA models, but those have problems too, listed below:

b5

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. b5

b5

b5 Thanks

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Sent: 2/25/2021 7:12:12 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
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Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,
Thanks so much for digging up the WG policies. They provide very helpful background. I look forward to speaking with you shortly.

Ann

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
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Hi—Bottom of page 2 of the policy: "The manner in which a working group functions, not the number of times it meets, determines whether or not it is exempt from the FACA."

Also, addendum is attached so we have everything.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 25, 2021 1:27 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Martin, Ann (NIH/OD) [E] b6
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Well, we wrote them into the stem cell policy and Jenny Spaeth approved it, so I'm not reopening that decision.

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
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Hi—Claire referred me to an OFACP policy on workgroups re: the temporary in nature: https://ofacp.od.nih.gov/pdfs/policy2000-01REVISED-WrkGroups-06-14-2005.pdf

Reading through this now...

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Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
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National Institutes of Health
Turning Discovery Into Health

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To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
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Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance
Attachments: WG_DSMB_Con Conf_IRB.pdf

Hi—What I wrote below is based on the attached document from OFACP files. I don't have any other background on this document, though.

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Hi, Ann! Tara and Larry want us to lay out all the options in one email which I am working on with Ellen and she would like to have one more chat and wants to understand more how DSMB's work in particular. I took a crack at starting something (see directly below) and Ellen is going to start wordsmithing this tomorrow. Our goal is to keep this as concise as possible.

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- 9:00
- Noon
- 2:30

FACA Options:

(b) (5)

(b) (5)

From: Martin, Ann (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 3:55 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
Thanks for the info below. I would be glad to talk with you and Claire about this on Monday. Would 11:30 or later work ok?
Hope you are doing well!
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 2:07 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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and I had a conversation with Ellen Gadbois and Michelle Culp yesterday about possible options if NIH were to form such a committee. The email Ellen sent to LAT below is based on that conversation.

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It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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Would you connect with Ann Martin on the following:

b5

I will respond to Tara on the 2nd paragraph.

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Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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From: Schwetz, Tara (NIH/OD) [E] < b6
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To: Harris, Claire (NIH/OD) [E] < b6 >
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

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Associate Deputy Director, NIH
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From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

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Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

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We briefly explored other non-FACA models, but those have problems too, listed below:
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In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
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Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8F38F3DA2FB3498F838FD8538DEA77F4-BRANDTP]
Sent: 2/25/2021 12:54:41 AM
To: Martin, Ann (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23b309bdbb1249d99e3ab0a7cd962332-martinad]
CC: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
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(b) (5)

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(b) (5)

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Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy

Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

National Institutes of Health
Turning Discovery into Health

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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Sent: 2/24/2021 9:40:31 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: FW: status of questions for Dr. Tabak on ACTIV biospecimen committee options

I guess this means Larry hasn't decided whether NIH or FNIH should do this? Anyway, I can draft up the two options and include the option of NIH doing it. I'll send it to you for your review.

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 4:35 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Harris, Claire (NIH/OD) [E] < b6 Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: Re: status of questions for Dr. Tabak on ACTIV biospecimen committee options

b5
b4

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Gadbois, Ellen (NIH/OD) [E]" b6
Date: Wednesday, February 24, 2021 at 11:25 AM
To: Tara Schwetz b6 >, "Harris, Claire (NIH/OD) [E]" < b6 >, "Brandt Hansberger, Patricia (NIH/OD) [E]" b6 >
Cc: "Culp, Michelle (NIH/OD) [E]" < b6
Subject: status of questions for Dr. Tabak on ACTIV biospecimen committee options

Dear all,

I understand that you have been thinking further about some options that Claire, Patti, Michelle and I discussed last week regarding a potential committee to vet requests for use of biospecimens from the ACTIV trials. I wanted to let you know that I actually have not heard anything from Dr. Tabak on whether he wants NIH (or FNIH) to stand up such a committee. b5 I then wrote to Dr. Tabak last Thursday (see below) with potential options and a request for guidance, and re-upped the question yesterday afternoon, but haven't received a response. So I don't know if we should sort things out further without some guidance from Dr. Tabak. He's presumably heard this whole presentation from FNIH but I don't know how he reacted. (I'm going to write to David Wholley next and will let you know what he says.)

So Tara, if you have the opportunity to ask Dr. Tabak what he thinks, that would be great. Please be aware that this committee would presumably need to be able to act quickly, so the model of having a Working Group to a FACA committee that only meets occasionally may be too slow. Presumably some of the leftover ACTIV research participant samples could be used to look at research questions related to emerging virus variants and other things that are happening fast. So as I think more about the options, I think having FNIH run this activity is still best, but presumably they need more resources to do so.

Happy to chat further.

Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 1:52 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi Larry,
I'm just upping this in your email. Please let us know if there's something we should do on this front.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
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Sent: 2/24/2021 2:22:25 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
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Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi—Claire just responded that she does not know if Tara and Larry have spoken.

From: Brandt Hansberger, Patricia (NIH/OD) [E]
Sent: Wednesday, February 24, 2021 9:12 AM
To: Gadbois, Ellen (NIH/OD) [E] < **b6**
Cc: Culp, Michelle (NIH/OD) [E] < **b6**
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Just emailed Claire and will let you know as soon as I hear back.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 9:01 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes but also I never received a response from LT regarding the email I sent him—which I also resent yesterday. Since he hopefully read that, and is also hearing directly from FNIH about the idea, I want to make sure that he and Tara have spoken to Tara is informed by whatever thoughts LT has had.

From: Brandt Hansberger, Patricia (NIH/OD) [E] < **b6**
Sent: Wednesday, February 24, 2021 8:59 AM
To: Gadbois, Ellen (NIH/OD) [E] < **b6**
Cc: Culp, Michelle (NIH/OD) [E] < b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I will ask Claire if Tara informed LAT that we connected with you and OGC about options and are pulling something together. I think that's what you meant on the "this" -- Just want to be sure!

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:56 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < **b6**
Cc: Culp, Michelle (NIH/OD) [E] < **b6**
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I'm tied up until 10 a.m. and should read through all this but then I'm free. Do we know if Tara has connected with Dr. Tabak on this?

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 >
Sent: Wednesday, February 24, 2021 8:54 AM
To: Gadbois, Ellen (NIH/OD) [E] < **b6** ; Culp, Michelle (NIH/OD) [E] b6

Cc: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good morning. Do you have time to connect this morning? I have a 11:00 – 11:30 meeting and then something 2:00 – 3:00, but my preference is to connect this morning since Claire would like to see if we could get something to Tara today.

Can we discuss how you would like to proceed putting together an options document for leadership. I am very flexible. Also, Claire wants me to get your thoughts in particular whether CoC is a good fit. She thinks the ACD would work as well but liked your input on the CoC. The charters are attached.

From: Harris, Claire (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:05 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] < **b6**
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Please see below. Please connect with Ellen and let her know of the 2 options and ask her if she wants to put together the summarizing document or if she wants us to start something and send to her to update, etc? Probably should get the document to Tara later today.

Thx

From: Schwetz, Tara (NIH/OD) [E] b6 v>
Sent: Wednesday, February 24, 2021 1:07 AM
To: Harris, Claire (NIH/OD) [E] b6 >
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Great. Are you pulling together a document summarizing the options? Or are Ellen and Michelle?

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" < **b6**
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To: Tara Schwetz b6 >
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Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

The working group option will work as well. Copying my comments from below: We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

In summary, I'm fine if the working group is needed for more than 1 year with a max of 2 years.

We will need to decide where Activ could fit. b5

b5

In summary, we have a non-FACA and FACA option to provide to FC.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Tuesday, February 23, 2021 2:22 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Claire,

Thanks – this does seem like a viable option.

What about the option to have a working group of a parent FACA committee? From my perspective (and from what I understand the intention to be), I think it would be fine if its membership was time-limited and only lasted 1-2 years. Is that not feasible? I want to ensure we lay out all of the potential options, with a recommendation as to which we think would best align with the goals of forming a committee/group and with FACA.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6 >
Date: Monday, February 22, 2021 at 2:11 PM

To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

Patti and I discussed your approach with Ann regarding an internal NIH committee with outside consultants providing individual perspectives. She thought it sounded fine with some reminders. As the committee would be comprised solely of Federal members, be mindful of communications with outside experts, e.g., when setting up a meeting, emails should be separate from the main committee; if two people with individual perspectives are invited to a meeting, send separate emails to avoid generating outside discussion. Ann also noted the importance of emphasizing that these individuals are consultants advising the committee, so be sure to have a record that the committee is asking for individual perspectives. In addition, she mentioned being mindful of implications under FOIA; however, it wasn't so much of a concern since this is an NIH committee with Federal members deliberating and providing recommendations that another official could act on. She added that the agency would have the argument that the consultants were hired by NIH to provide expertise to the committee.

So, this is a viable option for consideration by leadership. Wasn't sure if you wanted me to touch base with Ellen? Or wait until you had a chance to talk with LAT and make final decisions?

Best,

Claire

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 12:48 PM
To: Schwetz, Tara (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] <
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ok. Will connect with Ann.

Maybe some confusion re: subcommittees vs. WGs. We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

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Also, subcommittees follow most FACA rules, i.e. open to the public, meetings announced in FRN, minutes, etc.

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 11:38 AM

To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options b5 normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz < b6
Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee b5. You could have ad hocs on the subcommittee for their expertise but you wouldn't want to use the same ad hocs over and over again. If there was a need for separate membership from the parent committee then we would need to prepare a slate for HHS, get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. b5
b5

b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that (b) (5) to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. (b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:

(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

NIH National Institutes of Health
Turning Discovery Into Health

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8F38F3DA2FB3498F838FD8538DEA77F4-BRANDTP]
Sent: 2/24/2021 2:01:44 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK – did you/can you forward me the email you sent to him so I can see what you said?

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 9:01 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes but also I never received a response from LT regarding the email I sent him—which I also resent yesterday. Since he hopefully read that, and is also hearing directly from FNIH about the idea, I want to make sure that he and Tara have spoken to Tara is informed by whatever thoughts LT has had.

From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:59 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I will ask Claire if Tara informed LAT that we connected with you and OGC about options and are pulling something together. I think that's what you meant on the "this" -- Just want to be sure!

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:56 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I'm tied up until 10 a.m. and should read through all this but then I'm free. Do we know if Tara has connected with Dr. Tabak on this?

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Wednesday, February 24, 2021 8:54 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good morning. Do you have time to connect this morning? I have a 11:00 – 11:30 meeting and then something 2:00 – 3:00, but my preference is to connect this morning since Claire would like to see if we could get something to Tara today.

Can we discuss how you would like to proceed putting together an options document for leadership. I am very flexible. Also, Claire wants me to get your thoughts in particular whether CoC is a good fit. She thinks the ACD would work as well but liked your input on the CoC. The charters are attached.

From: Harris, Claire (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 8:05 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Please see below. Please connect with Ellen and let her know of the 2 options and ask her if she wants to put together the summarizing document or if she wants us to start something and send to her to update, etc? Probably should get the document to Tara later today.

Thx

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Wednesday, February 24, 2021 1:07 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Great. Are you pulling together a document summarizing the options? Or are Ellen and Michelle?

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Tuesday, February 23, 2021 at 8:53 AM
To: Tara Schwetz b6 >
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

The working group option will work as well. Copying my comments from below: We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

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We will need to decide where Activ could fit. Y b5

b5

In summary, we have a non-FACA and FACA option to provide to FC.

Best,

Claire

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Sent: Tuesday, February 23, 2021 2:22 AM
To: Harris, Claire (NIH/OD) [E] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

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What about the option to have a working group of a parent FACA committee? From my perspective (and from what I understand the intention to be), I think it would be fine if its membership was time-limited and only lasted 1-2 years. Is that not feasible? I want to ensure we lay out all of the potential options, with a recommendation as to which we think would best align with the goals of forming a committee/group and with FACA.

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A: Building 1, Room 138
P: b6 | M: b6

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Date: Monday, February 22, 2021 at 2:11 PM
To: Tara Schwetz <b6
Cc: "Harris, Claire (NIH/OD) [E]" <b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

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To: Schwetz, Tara (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] <
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, (b) (5) We normally form working groups with 1 or 2 members from the parent

committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

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P: b6 | **M:** b6

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Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

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(b) (5)

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Tara A. Schwetz, PhD
Associate Deputy Director, NIH

A: Building 1, Room 138
P: b6 | M: b6 0

From: "Harris, Claire (NIH/OD) [E]" < b6
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To: Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
options/need guidance

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(b) (5)

(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 2/18/2021 2:42:44 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: your thoughts on biospecimen prioritization committee idea?

It's across 2 and 3...and soon will oversee 6 as well.

From: Gadbois, Ellen (NIH/OD) [E] <b6
Sent: Thursday, February 18, 2021 9:40 AM
To: Read, Sarah (NIH/NIAID) [E] <b6
Cc: Culp, Michelle (NIH/OD) [E] <b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Thanks, Sarah. Is the Trial Oversight Committee across all ACTIV trials, or does each ACTIV trial have its own? (I know there is some cross-trial group...)

From: Read, Sarah (NIH/NIAID) [E] b6
Sent: Thursday, February 18, 2021 8:29 AM
To: Adam, Stacey (FNIH) [T] b6 >; Gadbois, Ellen (NIH/OD) [E] <b
Cc: Culp, Michelle (NIH/OD) [E] b6 >
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Stacey, I'm not really sure what I was thinking...and in fact, can't really think of a way to use the committee as a go-between since they are largely NIHers.

From: Adam, Stacey (FNIH) [T] < b6
Sent: Wednesday, February 17, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] b6 >; Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi All,

Thanks for keeping me in the loop.

Sarah, not sure on the TOC. Did you have a notion to have it replace the oversight committee or something else?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: b6 | Mobile: (b6

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Wednesday, February 17, 2021 4:50 PM
To: Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 Adam, Stacey (FNIH) [T] b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Thanks, Sarah. FYI NIH has working groups of FACA committees that develop "findings" or do "analysis" and/or collect individual views, but a formal consensus recommendation to NIH only comes from a FACA Committee. BUT there is probably a way for a group to advise the investigators themselves (not NIH), which is essentially how the partnerships work where the steering committees can provide direction to investigators. Anyway, I am trying to get more information/ideas on a few ideas. I was just hoping there was some existing structure we could use. Interestingly DSMBs are not FACA committees.

From: Read, Sarah (NIH/NIAID) [E] b6
Sent: Wednesday, February 17, 2021 2:41 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Adam, Stacey (FNIH) [T] < b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi Ellen,
Thank you for your thoughts on this committee and for pointing out possible pitfalls. I'm cutting and pasting your questions below with my answers alongside:

(b) (5)

Is there a work around...Can we call the output of the group something other than "recommendations?" Perhaps we can combine what are now being called Oversight Committee and Review Committee (see slide 6) into one and say that NIH members are "voting" members but academic/industry reps are not?

I'm copying Stacey to for her awareness and input if she has any ideas. Stacey, I'm wondering if there might be a role for the Trial Oversight Committee in this somehow?

I'm also happy to get on a call if that would be easier but am pretty booked today and tomorrow...I do have time on Friday.

Thanks,
Sarah

From: Gadbois, Ellen (NIH/OD) [E] < b6 >
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: your thoughts on biospecimen prioritization committee idea?

Oops—resending because I had meant to cc Michelle.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] < b6
Subject: your thoughts on biospecimen prioritization committee idea?

Dear Sarah,

Michelle and I understand from David Wholley that Cliff Lane wants to establish a biospecimen prioritization committee to handle requests to use biospecimens collected in the ACTIV trials. David sent Michelle the attached slides describing the plan and a message below. I know the general plan has also been discussed in the ACTIV therapeutics working group.

The draft plan (b) (5)
(b) (5)

Happy to get on the phone if this is easier to discuss, or let me know if I should contact someone else at NIAID.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] <d b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6 >
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Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

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I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8F38F3DA2FB3498F838FD8538DEA77F4-BRANDTP]
Sent: 2/18/2021 2:12:20 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: biospecimen prioritization committee--how could we implement?

OK – I just sent Claire an email. We are in the midst of this data call which is due to EDI today and it's pretty crazy right now, but I offered to set up a quick call to talk this through. I mentioned how this is kind of time sensitive because FC could be asked by David Wholley.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 9:09 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Thanks. Yes I only brought up IRBs because they were mentioned in at attachment. Just disregard my IRB question for now—it's probably not central to what we are trying to figure out.
Thanks again

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6 >
Sent: Thursday, February 18, 2021 9:05 AM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: RE: biospecimen prioritization committee--how could we implement?

Hi-I am just about to send her an email. I didn't think IRBs were the focus of your question? Are you asking because they are in the attachment?

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 9:04 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: RE: biospecimen prioritization committee--how could we implement?

Thanks, Patti—that's very helpful. Would you be able to talk to Claire today or do you want me to email her and cc you?

One thing I don't understand is how the intramural IRB(s) fit into this, since they are reporting to NIH...

From: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 8:57 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 ov>; Brandt Hansberger, Patricia (NIH/OD) [E] b6 >
Subject: RE: biospecimen prioritization committee--how could we implement?

Good morning – I am looking through the files on OFACP's shared drive and found the attached which mentions DSMBs, which may be helpful. Also, FYI, see 2nd attachment which lists activities not covered by FACA and slides 22 and 23 from the third attachment which was from a PO training from last May that Claire participated in.

In any event, these options look like you are on the right track to me and I'm sure Claire will have other thoughts.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 4:59 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: biospecimen prioritization committee--how could we implement?

Hi Patti,
Thanks for the quick chat this afternoon. Here's the issue in a nutshell:

b5

b5 . However, the draft plan includes academic and industry members. We are trying to figure out how this could be implemented given that any formal recommendations to NIH would presumably need to go through a federal advisory committee per FACA. We don't want to have to establish a new FACA.

So here are the other paths I'm thinking about:
(b) (5)

Any ideas you and/or Claire have are welcome. Happy to get on the phone again.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Read, Sarah (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=527B160038004A199AE6E0BAC2226099-READSA]
Sent: 2/18/2021 1:26:14 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Thanks Ellen. Having the groups advise the investigators (ie the clinical trials teams), as opposed to NIH, might be a good solution.

Sarah

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 4:50 PM
To: Read, Sarah (NIH/NIAID) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Adam, Stacey (FNIH) [T] < b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Thanks, Sarah. FYI NIH has working groups of FACA committees that develop "findings" or do "analysis" and/or collect individual views, but a formal consensus recommendation to NIH only comes from a FACA Committee. BUT there is probably a way for a group to advise the investigators themselves (not NIH), which is essentially how the partnerships work where the steering committees can provide direction to investigators. Anyway, I am trying to get more information/ideas on a few ideas. I was just hoping there was some existing structure we could use. Interestingly DSMBs are not FACA committees.

From: Read, Sarah (NIH/NIAID) [E] < b6
Sent: Wednesday, February 17, 2021 2:41 PM
To: Gadbois, Ellen (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 Adam, Stacey (FNIH) [T] < b6
Subject: RE: your thoughts on biospecimen prioritization committee idea?

Hi Ellen,
Thank you for your thoughts on this committee and for pointing out possible pitfalls. I'm cutting and pasting your questions below with my answers alongside:

(b) (5)

Is there a work around...Can we call the output of the group something other than "recommendations?" Perhaps we can combine what are now being called Oversight Committee and Review Committee (see slide 6) into one and say that NIH members are "voting" members but academic/industry reps are not?

I'm copying Stacey to for her awareness and input if she has any ideas. Stacey, I'm wondering if there might be a role for the Trial Oversight Committee in this somehow?

I'm also happy to get on a call if that would be easier but am pretty booked today and tomorrow...I do have time on Friday.

Thanks,
Sarah

From: Gadbois, Ellen (NIH/OD) [E] b6 >
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >
Subject: FW: your thoughts on biospecimen prioritization committee idea?

Oops—resending because I had meant to cc Michelle.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, February 17, 2021 10:30 AM
To: Read, Sarah (NIH/NIAID) [E] b6
Subject: your thoughts on biospecimen prioritization committee idea?

Dear Sarah,

b5

b5 I know the general plan has also been discussed in the ACTIV therapeutics working group.

The draft plan includes (b) (5)
(b) (5)

Happy to get on the phone if this is easier to discuss, or let me know if I should contact someone else at NIAID.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] < b6 >
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5

b5 Thanks

From: Brandt Hansberger, Patricia (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8F38F3DA2FB3498F838FD8538DEA77F4-BRANDTP]
Sent: 2/18/2021 3:52:20 AM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: biospecimen prioritization committee--how could we implement?

Great to chat with you today. I just finished reviewing a bunch of info for a data request and will look into this when I am fresh in the morning.

Talk to you soon!

Patti

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 4:59 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: biospecimen prioritization committee--how could we implement?

Hi Patti,
Thanks for the quick chat this afternoon. Here's the issue in a nutshell:

b5

b5 However, the draft plan includes academic and industry members. We are trying to figure out how this could be implemented given that any formal recommendations to NIH would presumably need to go through a federal advisory committee per FACA. We don't want to have to establish a new FACA.

So here are the other paths I'm thinking about:

(b) (5)

Any ideas you and/or Claire have are welcome. Happy to get on the phone again.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] < b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6

Cc: Adam, Stacey (FNIH) [T] < b6

Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,

I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

(b) (5)

b5 Thanks

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 2/17/2021 3:42:14 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: draft email for Sarah--your thoughts on biospecimen prioritization committee idea?

Sorry, Ellen.
I reviewed the draft on my phone yesterday when the VPN was down and then didn't reply. Thanks for moving this along.

Get Outlook for iOS

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, February 17, 2021 10:27:37 AM
To: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: draft email for Sarah--your thoughts on biospecimen prioritization committee idea?

I think I'm going to go ahead with this—hopefully it is clear.

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, February 17, 2021 7:14 AM
To: Culp, Michelle (NIH/OD) [E] < b6
Subject: FW: draft email for Sarah--your thoughts on biospecimen prioritization committee idea?

Hi Michelle—do you have any edits on this? I'd like to email Sarah this morning.
Thanks,
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Tuesday, February 16, 2021 1:36 PM
To: Culp, Michelle (NIH/OD) [E] b6
Subject: draft email for Sarah--your thoughts on biospecimen prioritization committee idea?

Dear Sarah,

b5

The draft plan includes (b) (5)

(b) (5)

Happy to get on the phone if this is easier to discuss.
Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

b5 Thanks

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 2/16/2021 4:14:46 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: FW: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx
Attachments: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

See slide 6

From: Wholley, David (FNIH) [T] < b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] < b6
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)
(b) (5)

b5 Thanks

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 2/24/2021 11:18:11 AM
To: Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks!

From: "Schwetz, Tara (NIH/OD) [E]" <tara. b6
Date: Wednesday, February 24, 2021 at 1:06 AM
To: "Tabak, Lawrence (NIH/OD) [E]" < b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – I've asked Claire for a succinct summary of the options.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Tuesday, February 23, 2021 at 8:53 AM
To: Tara Schwetz <tara. b6
Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

The working group option will work as well. Copying my comments from below: We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

In summary, I'm fine if the working group is needed for more than 1 year with a max of 2 years.

We will need to decide where Activ could fit. You mentioned ACD or CoC. I've copied the Description of Duties from the CoC Charter:

DESCRIPTION OF DUTIES

The Council advises on matters related to the policies and activities of DPCPSI, including making recommendations with respect to the conduct and support of research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or

supporting additional research that involves collaboration between two or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning.

In summary, we have a non-FACA and FACA option to provide to FC.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Tuesday, February 23, 2021 2:22 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Claire,

Thanks – this does seem like a viable option.

What about the option to have a working group of a parent FACA committee? From my perspective (and from what I understand the intention to be), I think it would be fine if its membership was time-limited and only lasted 1-2 years. Is that not feasible? I want to ensure we lay out all of the potential options, with a recommendation as to which we think would best align with the goals of forming a committee/group and with FACA.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | **M:** b6

From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Monday, February 22, 2021 at 2:11 PM
To: Tara Schwetz b6
Cc: "Harris, Claire (NIH/OD) [E]" < b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

Patti and I discussed your approach with Ann regarding an internal NIH committee with outside consultants providing individual perspectives. She thought it sounded fine with some reminders. As the committee would be comprised solely of Federal members, be mindful of communications with outside experts, e.g., when setting up a meeting, emails should be separate from the main committee; if two people with individual perspectives are invited to a meeting, send separate emails to avoid generating outside discussion. Ann also noted the importance of emphasizing that these individuals are consultants advising the committee, so be sure to have a record that the committee is asking for individual perspectives. In addition, she mentioned being mindful of implications under FOIA; however, it wasn't so much of a concern since this is an NIH committee with Federal members deliberating and providing recommendations that another official could act on. She added that the agency would have the argument that the consultants were hired by NIH to provide expertise to the committee.

So, this is a viable option for consideration by leadership. Wasn't sure if you wanted me to touch base with Ellen? Or wait until you had a chance to talk with LAT and make final decisions?

Best,

Claire

From: Harris, Claire (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 12:48 PM
To: Schwetz, Tara (NIH/OD) [E] b6
Cc: Harris, Claire (NIH/OD) [E] <
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ok. Will connect with Ann.

Maybe some confusion re: subcommittees vs. WGs. We can use the working group structure but it's my understanding that these biospecimen requests/meetings will be needed for quite some time. WGs are usually temporary in nature so we would need to have perhaps one Working Group per year. As an example, ACTIV Biospecimens 1 and terminate after a year. Create WG 2; ACTIV Biospecimens 2, working group membership should be a different, etc.

Subcommittees are a bit different and more formal. Here is the standard language from charters:

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. Ad hoc consultants do not count towards the quorum and may not vote. A quorum for a subcommittee will be three members. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Also, subcommittees follow most FACA rules, i.e. open to the public, meetings announced in FRN, minutes, etc.

Claire

From: Schwetz, Tara (NIH/OD) [E] b6 >
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, (b) (5) We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (https://acd.od.nih.gov/working-groups.html). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138

P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz < b6
Cc: "Harris, Claire (NIH/OD) [E]" b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee b5 You could have ad hocs on the subcommittee for their expertise but you wouldn't want to use the same ad hocs over and over again. If there was a need for separate membership from the parent committee then we would need to prepare a slate for HHS, get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] < b6
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. b5

b5

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6

From: "Harris, Claire (NIH/OD) [E]" b6
Date: Thursday, February 18, 2021 at 5:46 PM

To: Tara Schwetz b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that (b) (5) to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. (b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:
(b) (5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,

Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6 >
Cc: Adam, Stacey (FNIH) [T] < b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions (b) (5)
(b) (5)

b5 Thanks

Sent: 5/27/2020 12:05:42 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers
Attachments: jama_collins_stoffels_2020_vp_200113.pdf

Hi Francis,

We will put together 7-8 slides on ACTIV for the Hever meeting and send for your review—final slides are due before noon on Monday.

Pre-reads are due by COB tomorrow. Attached is the JAMA article if you haven't already shared.

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Monday, May 25, 2020 2:01 PM
To: Wholley, David (FNIH) [T] < b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: FW: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

See instructions below from Sogaard about the coming Hever meeting. All this seems a bit over the top in prescribing the format, but ok.

With just 15 minutes for the ACTIV presentation, I would think we should use 5 or 6 slides about the overall status of the effort, and then a final slide or two on the mAb trials (since that is the request for focus). It would be great to have help from you two for that.

For the pre-read, I would think the JAMA article would be just fine. If you agree, I can send that to Morten now.

FC

From: b6 b6
Sent: Monday, May 25, 2020 12:58 PM
To: b6 Collins, Francis (NIH/OD) [E] < b6 Woodcock, Janet (FDA/CDER) < b6 Stoffels, Paul [JJCUS] < b6 Plump, Andrew < b6
Cc: b6 b6 b6 FMedSci Trevor < b6 b6 b6
Subject: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Dear All,

As we are getting closer to our June 2 HEVER COVID-19 meeting we are working to shore up the logistics for the meeting.

To that end we would like to ask you to

- Indicate if you plan to circulate pre-reads – if you are could you kindly submit them by Thursday May 28th End of Day EDT – so we can collate and send them out to the full team.

- Submit presentation slides by Monday June 1 by noon EDT at the latest – so we can collate into a master deck for efficient running of the meeting on June 2.

As you know we are working to set up a 30 min check-in meeting end of next week for presenters. Awaiting scheduling of this and realizing that it may be challenging to get on all calendars – we wanted to provide some guide lines (but ultimately your call)

- The meeting is scheduled to be 105 min but we are hoping that we might end at 90 minutes if we are disciplined.
- For the presentation we would recommend a few set up slides leading to one discussion slides outlining on the key proposals for the HEVER+ group to align on, and more detailed information in the pre-read.

Kindly submit slides to b6 and Jill Payne cc to b6 and Trevor Jones

Best regards,
Morten on behalf of the team

Agenda for Hever Group video WebEx on 2nd June ~ 90 min discussion (planned for 105 min, but hoping to end early)

- Setting the stage (b6 *5 min*
- Update on coordination of US COVID Initiatives (Moncef Slaoui) *10 min*
- Update on Covid R&D consortium ...pre-circulated **Clinical Trial Acceleration Overview** Update (Andy Plump)....Update on ACTIV trials with focus on new mAb master protocol (Francis Collins tbc) *30 min (15- + 15)*
- **Regulatory streamlining** of COVID-19 Clinical Trials (Janet Woodcock w/ commentaries from key regulatory colleagues) *20 min*
- **Data sharing** ... review and suggestions for the way forward (Andy Plump) and **Accumulus overview** incl. alignment w/ data repository landscape (Paul Stoffels) *40 min* (20 + 20)

From: b6 b6
Sent: Sunday, August 30, 2020 10:56 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Sogaard, Morten b6 ;
Parker, Ashley (NIH/OD) [E] b6
George, Jill (NIH/OD) [E] b6 >; Trevor
Jones b6 ;
; Geoff Frew
b6
Subject: Re: [EXTERNAL] RE: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Good suggestion

Maybe we can group drugs to be tested in order to make cross presenter summary

Known viral targets
Host targets
Unknown MOA

Or any other matrix you prefer

Sent from my iPhone

> On Aug 30, 2020, at 09:49, Collins, Francis (NIH/OD) [E] b6 wrote:
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> Ashley can get slides to you by tomorrow.
>
> Francis

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b6
Sent: Sunday, August 30, 2020 9:16 AM
To: Collins, Francis (NIH/OD) [E]
b6 >
Cc: Parker, Ashley (NIH/OD) [E]
b6 >; George, Jill
(NIH/OD) [E] b6 ;
b6
b6 >; Trevor
Jones
< b6 ;
b6 ; Geoff Frew
b6 >;
b6
b6 >
Subject: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Dear Francis

I hope this e-mail is reaching you well.

I understand from Trevor that he had agreed with you to do a quick update on antivirals ACTIV activities and plans as part of the discussion session in Wednesday session.

So just checking in if you would plan to have pre-read slides, and also if you plan to have presentation slides or run the discussion without slides?
I think planning for ~ 5 minutes so as part of the discussion probably will be appropriate. We only have 1 hour for this next meeting – so a bit shorter than previous meetings.

It would be great if you could let us know if you plan to have presentations slides so that we can integrate those.

Also if Ashley could help send pre-read slides to myself and Jill cc to Trevor ideally by Monday 5 pm EST.

Please, see current draft agenda below.

Looking forward to an exciting discussion.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Sunday, August 30, 2020 2:28 PM
To: Collins, Francis (NIH/OD) [E] b6 ;
Wholley, David (FNIH) [T] < b6 ;
Menetski, Joseph (FNIH) [T] b6 ;
Adam, Stacey (FNIH) [T] b6 .
Subject: RE: [EXTERNAL] RE: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Hi Francis,

We will take care of it and send a version back to you for review.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E]
b6
Sent: Sunday, August 30, 2020 2:26 PM
To: Parker, Ashley (NIH/OD) [E]
b6 >; Wholley, David (FNIH) [T]
b6 ; Menetski, Joseph (FNIH) [T]
< b6 ; Adam, Stacey (FNIH) [T]
< b6
Subject: FW: [EXTERNAL] RE: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Is it possible to group the antivirals from Waves 1 – 3 with these categories? Aren't they mostly "known viral targets"?

FC

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Sent: Sunday, August 30, 2020 10:56 AM
To: Collins, Francis (NIH/OD) [E] b6 >
Cc: Sogaard, Morten b6
Parker, Ashley (NIH/OD) [E] b6 ;
George, Jill (NIH/OD) [E] b6 >; Trevor Jones < b6 ;
b6 ; Geoff Frew
< b6
Subject: Re: [EXTERNAL] RE: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

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> **To:** Collins, Francis (NIH/OD) [E] < b6
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b6

Subject: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Dear Francis

I hope this e-mail is reaching you well.

I understand from Trevor that he had agreed with you to do a quick update on antivirals ACTIV activities and plans as part of the discussion session in Wednesday session.

So just checking in if you would plan to have pre-read slides, and also if you plan to have presentation slides or run the discussion without slides?
I think planning for ~ 5 minutes so as part of the discussion probably will be appropriate. We only have 1 hour for this next meeting – so a bit shorter than previous meetings.

It would be great if you could let us know if you plan to have presentations slides so that we can integrate those.

Also if Ashley could help send pre-read slides to myself and Jill cc to Trevor ideally by Monday 5 pm EST.

Please, see current draft agenda below.

Looking forward to an exciting discussion.

Best wishes on behalf of b6 and Trevor,
b6

<image001.jpg>

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 5/3/2020 9:08:16 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] Covid-19 Datasharing

This is interesting and related to some aspects of the TransNIH5 (Data) group's work. I would like to share with them and get their feedback if the presentation is shareable – it is labelled "Confidential – Do not distribute". I am happy to ask Morten if it's ok to share with TransNIH5 but will defer to David or someone else if more appropriate to do so.
Chris

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Saturday, May 2, 2020 3:32 PM
To: Wholley, David (FNIH) [T] < b6
Cc: Tabak, Lawrence (NIH/OD) [E] < b6 Austin, Christopher (NIH/NCATS) [E] < b6 Lane, Cliff (NIH/NIAID) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6 Anderson, James (NIH/OD) [E] < b6 Freire, Maria (FNIH) [T] < b6
Subject: FW: [EXTERNAL] Covid-19 Datasharing

Can you discuss this with the ACTIV team?

From: b6 b6
Sent: Saturday, May 2, 2020 2:52 PM
To: Prof Trevor M Jones CBE FMedSci < b6 Andrew Plump < b6 Collins, Francis (NIH/OD) [E] < b6 b6 b6 paul stoffel < b6
Cc: Geoff Frew < b6 Jill Payne < b6 b6 < b6
Subject: RE: [EXTERNAL] Covid-19 Datasharing

Dear All,

I hope you are all having a good weekend.

A couple of additional thoughts on the data sharing front:

We had a discussion internally in Pfizer about the Accumulus regulatory cloud proposal that Paul and J&J have been putting together – as part of that discussion the team (J&J/Deloitte) had come up with an idea to use aggregation of

COVID-19 data to get this platform of the ground (see enclosed). Could be that this may be too ambitious timewise to leverage w/ COVID-19 but I thought it was an interesting proposal. Are there other data aggregation platforms for clinical data that we could leverage – Vivli etc?

Another idea is that we could offer the UK Biobank to use a data sharing platform / portal developed by Pfizer with the Broad Institute and a few industry partners for genetic / UK Biobank data to share industry-sponsored exome data and COVID-19 patient data that UK Biobank has collected on study participants (would need to check if the UK Biobank is OK with this).

Third reflection is whether there are insights from Andy and the COVID-19 R&D consortium eg based on the nice work on a COVID-19 R&D data WIKI on specific overlaps in the therapeutics and clinical trial areas across the different initiatives that we could bring up in brief e-mail exchanges such as this one w/a few of the colleagues?

On the data sharing front you have clearly taken the lead, Andy. Any other recommendations for actions to drive across initiatives from you or other colleagues on the line?

Best Regards,

b6

From: Prof Trevor M Jones CBE FMedSci < b6
Sent: Thursday, April 30, 2020 11:49 AM
To: Andrew Plump < b6 b6 b6 b6
paul stoffel < b6
Cc: b6 < b6 Geoff Frew < b6 Jill Payne
< b6
Subject: [EXTERNAL] Covid-19 Datasharing

TransCelerate has announced its intentions on COVID Data Sharing.

Link here: https://www.businesswire.com/news/home/20200415005128/en/TransCelerate-BioPharma-Member-Companies-Commit-Share-COVID-19

Prof Trevor M Jones CBE FMedSci

Sent: 1/14/2021 11:04:52 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: URGENT: Need for slides for Hever Covid Teleconference 6 19th January 2021
Attachments: DRAFT HEVER January 19, 2021 COVID-19 Meeting_Presentation_FRANCIS COLLINS 011421.pptx

Hi Francis,

Please see the attached draft slides for the Hever meeting next Tuesday, 1/19. We figured you wouldn't spend much time on the intro and focus on slides 4-10.

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Thursday, January 14, 2021 12:03 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Wholley, David (FNIH) [T] < b6
Subject: RE: URGENT: Need for slides for Hever Covid Teleconference 6 19th January 2021

That would be great. Please work with David to see what can be assembled.

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Thursday, January 14, 2021 11:07 AM
To: Collins, Francis (NIH/OD) [E] < b6 Wholley, David (FNIH) [T] < b6
Subject: RE: URGENT: Need for slides for Hever Covid Teleconference 6 19th January 2021

I had to drop off the ACTIV EC/LT meeting to join the HHS mAb media conference but I am happy to help pull together a few slides based on what captured the most interest today.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Thursday, January 14, 2021 9:09 AM
To: Wholley, David (FNIH) [T] < b6
Cc: Parker, Ashley (NIH/OD) [E] < b6
Subject: URGENT: Need for slides for Hever Covid Teleconference 6 19th January 2021

Hi David,

I have been remiss in not reaching out sooner about this request for slides for the Hever meeting on January 19. b6 wants these by tomorrow (yikes!).

I would think that 7 – 8 slides from today's LT meeting could be adapted for the ACTIV presentation – we can see what topics seem to have captured the most interest today.

For AMP-Common Metabolic Disease, there are presumably 7 – 8 slides from the most recent AMP ExComm that can be adapted. I'm not entirely clear why this is being featured at Hever – but I assume this is an opportunity to encourage companies to sign up. That's not something I can do – is b6 prepared to make the ask?

Ashley is totally ready to help assemble these presentations.

Thanks, and apologies for the short lead time.

Francis

From: b6 <b6
Sent: Thursday, January 14, 2021 7:59 AM
To: Parker, Ashley (NIH/OD) [E] <b6
Cc: Jill Payne <b6 Collins, Francis (NIH/OD) [E] <b6 Sogaard, Morten <b6
Subject: RE: Hever Covid Teleconference 6 19th January 2021

Dear Ashley,

I hope all is well !

Just checking in on when we can expect the slides for Francis' two presentations for next Tuesday's HEVER meeting Ideally in ppt format) as well as any pertinent pre-read information.

2.2 NIH/ACTIV Francis Collins 15 min (11.55 – 12.10 pm)
3.1 AMP Common Metabolic Diseases (T2D 2.0) programme Francis Collins (12.25 – 12.40 pm)

We were hoping that we could have all the slides collected for circulation by tomorrow Friday.

Thank you for your help and best regards,
Morten

From: Jill Payne <b6
Sent: Tuesday, January 12, 2021 12:14 PM
To: Jill Payne <b6
Cc: b6 <b6
Subject: [EXTERNAL] Hever Covid Teleconference 6 19th January 2021

Please find attached the latest agenda for the call on the 19th January.

It would be extremely helpful to have your presentations by Friday noon (Eastern time), so that they can be distributed to the Hever members as pre-reads with plenty of time for them to read through them.

Please send to me and also to Morten Sogaard who is copied above.

Many thanks for your assistance.

Kind regards

Jill Payne
On behalf of Hever

Email: b6

Cell: b6

Is it possible to group the antivirals from Waves 1 – 3 with these categories? Aren't they mostly "known viral targets"?

FC

From: b6 b6
Sent: Sunday, August 30, 2020 10:56 AM
To: Collins, Francis (NIH/OD) [E] b6
Cc: b6 b6 ; Parker, Ashley (NIH/OD) [E] b6 George, Jill (NIH/OD) [E] b6 >; Trevor Jones b6 >; b6 Geoff Frew b6
Subject: Re: [EXTERNAL] RE: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Good suggestion

Maybe we can group drugs to be tested in order to make cross presenter summary

Known viral targets
Host targets
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Or any other matrix you prefer

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<b6
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b6 ; Trevor Jones
b6
b6 Geoff Frew
<b6
b6
b6
Subject: HEVER COVID-19 Antivirals meeting Sept 2 - Slides

Dear Francis

I hope this e-mail is reaching you well.

I understand from Trevor that he had agreed with you to do a quick update on antivirals ACTIV activities and plans as part of the discussion session in Wednesday session.

So just checking in if you would plan to have pre-read slides, and also if you plan to have presentation slides or run the discussion without slides?
I think planning for ~ 5 minutes so as part of the discussion probably will be appropriate. We only have 1 hour for this next meeting – so a bit shorter than previous meetings.

It would be great if you could let us know if you plan to have presentations slides so that we can integrate those.

Also if Ashley could help send pre-read slides to myself and Jill cc to Trevor ideally by Monday 5 pm EST.

Please, see current draft agenda below.

Looking forward to an exciting discussion.

Best wishes on behalf of b6 l and Trevor,
b6

<image001.jpg>

Sent: 4/22/2020 10:33:58 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Preparation for HEVER COVID-19 call
Attachments: HEVER slides_ACTIV April 23, 2020.pptx; Short Version of HEVER slides_ACTIV April 23, 2020.pptx

Hi Francis,

With many thanks to Jill for converting these – please see attached slides for the HEVER COVID-19 meeting tomorrow.

I've attached 2 versions – the email below from Morten explains you have 15 minutes followed by Q&A (please see 1st attachment with 14 slides). If you plan to present in 7-8 mins – please see 2nd attachment with

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, April 22, 2020 2:20 PM
To: Collins, Francis (NIH/OD) [E] < b6 Wholley, David (FNIH) [T] < b6
Cc: Tabak, Lawrence (NIH/OD) [E] < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Preparation for HEVER COVID-19 call

Yes – Jill and I are already working on moving your slides into your background and we will work on trimming/reformatting the slides.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, April 22, 2020 2:17 PM
To: Wholley, David (FNIH) [T] b6 Parker, Ashley (NIH/OD) [E] < b6
Cc: Tabak, Lawrence (NIH/OD) [E] < b6 George, Jill (NIH/OD) [E] < b6
Subject: RE: Preparation for HEVER COVID-19 call

I think that should be fine. Ashley, can you take the first crack on picking out a set that I could present in 7 – 8 minutes? I'm looping in Jill George to put her on alert that we'll need her help on reformatting.

FC

From: Wholley, David (FNIH) [T] < b6
Sent: Wednesday, April 22, 2020 12:54 PM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: Parker, Ashley (NIH/OD) [E] < b6 Tabak, Lawrence (NIH/OD) [E] < b6
Subject: RE: Preparation for HEVER COVID-19 call

So you are just going to select what you need out of today's call and have your staff put them in the NIH format? Just want to be clear.

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Wednesday, April 22, 2020 12:29 PM
To: Wood, Gretchen (NIH/OD) [E] < b6
Cc: McManus, Ayanna (NIH/OD) [E] < b6 Tabak, Lawrence (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6 Wholley, David (FNIH) [T] < b6
Subject: RE: Preparation for HEVER COVID-19 call

Yes, I will use slides, but they won't be ready until tomorrow.

From: Wood, Gretchen (NIH/OD) [E] < b6
Sent: Wednesday, April 22, 2020 12:01 PM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: McManus, Ayanna (NIH/OD) [E] < b6 Tabak, Lawrence (NIH/OD) [E] < b6
Subject: Re: Preparation for HEVER COVID-19 call

Thanks, Francis. The HEVER team wants to know if you intend to use slides or have any background materials to share for that meeting. They would like them today, if possible.

From: Francis Collins < b6
Date: Wednesday, April 22, 2020 at 11:13 AM
To: Gretchen Wood b6
Cc: "McManus, Ayanna (NIH/OD) [E]" < b6 "Tabak, Lawrence (NIH/OD) [E]" < b6
Subject: RE: Preparation for HEVER COVID-19 call

Yes, I am available and will have to skip the Response Team call on Friday.

From: Wood, Gretchen (NIH/OD) [E] < b6
Sent: Wednesday, April 22, 2020 9:57 AM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: McManus, Ayanna (NIH/OD) [E] < b6
Subject: FW: Preparation for HEVER COVID-19 call
Importance: High

Good morning, Francis,

Apologies for my confusion about this. Are you able to participate in this call starting at 7:30 AM on Friday? I thought I had seen another entry that had to do with a white paper last week. Appreciate your guidance.

From: b6 b6
Date: Tuesday, April 21, 2020 at 10:09 AM
To: Gretchen Wood < b6 "McManus, Ayanna (NIH/OD) [E]" < b6
Subject: FW: Preparation for HEVER COVID-19 call

Dear Gretchen/Ayanna,

I am following up on Morten's e-mail below regarding a HEVER COVID-19 meeting that is scheduled for Friday, April 24th at 7:30am EST. The meeting will take place with b6 from Pfizer and with about 25 other

pharmaceutical leaders. Can you please confirm that Dr. Collins is indeed available at that time. I will send an invitation and dial-in instructions shortly.

Thank you and regards,

b6

From: b6 b6
Sent: Monday, April 20, 2020 11:21 PM
To: Collins, Francis (NIH/OD) [E] <coll b6
Cc: b6
b6 Giurdanella, Rosetta < b6 b6
< b6
Subject: Preparation for HEVER COVID-19 call

Dear Francis,

I hope all is well.

I am writing to follow up on your conversation with b6 about the upcoming HEVER COVID-19 meeting on Friday 7.30 a.m. EST.

The current thinking is that b6 will kick off the meeting to set the stage and that you would then give an overview of the ACTIV initiative - 15 minutes or so. This would be followed by a discussion with the broader group on actions that could be taken to align COVID-19 collaborative initiatives.
Andy Plump will be able to join for the first 30 minutes and is interested in contributing one or two slides on his initiative, which we could take either before your presentation or after.

We would like to ideally circulate slides by the end of Wednesday and were hoping that this might be acceptable, otherwise please let us know.
Because of the set up (WebEx) we would like to make sure that colleagues who have technical difficulties with the WebEx will be able to dial in and see the pre-circulated slides.

I cc Ayanna as well as Rosetta and Ann at our end for help with follow up.

Best Regards and Thank You, on behalf of b6 and myself,

b6

Sent: 4/22/2020 10:33:35 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Preparation for HEVER COVID-19 call
Attachments: HEVER slides_ACTIV April 23, 2020.pptx; Short Version_HEVER slides_ACTIV April 23, 2020.pptx

Hi Francis,

With many thanks to Jill for converting these – please see attached slides for the HEVER COVID-19 meeting tomorrow.

I've attached 2 versions for your consideration. The email below from Morten explains you have 15 minutes followed by Q&A – please see 1st attachment with 14 slides. If you plan to present in 7-8 mins – please see 2nd attachment with 9 slides.

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Cc: "McManus, Ayanna (NIH/OD) [E]" < b6 "Tabak, Lawrence (NIH/OD) [E]"
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Cc: McManus, Ayanna (NIH/OD) [E] < b6
Subject: FW: Preparation for HEVER COVID-19 call
Importance: High

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Date: Tuesday, April 21, 2020 at 10:09 AM

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Cc: b
b6 b6 b6 b6
< b6
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(b) (6)

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To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Kamphaus, Tania (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af5446a0db6a49499cfe3613cab9c610-kamphaustn]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: Re: [EXTERNAL] Short presentation on AMP Common Metabolic Disorders (AMP CMD) tomorrow

Happy to do a few slides and end w the fund raising

We plan to participate

Sent from my iPhone

> On Jan 14, 2021, at 20:26, Wholley, David (FNIH) [T] < b6 wrote:
>
> Hi b6
> First of all, Tania Kamphaus here on our FNIH team tells me that we have recently been given at least a verbal signal that Pfizer intends to support the AMP CMD effort. Thank you so much for your support!
>
> As you may recall, on our last AMP EC meeting we agreed that the AMP CMD effort would be brought to discussion at the next Hever meeting with the idea of seeing if we can rally a few additional funders and move it forward toward launch. I understand that the meeting has been scheduled for this Tuesday, January 19, and that slides have been requested to be sent in by tomorrow morning. To that end, we have put together the attached slide deck. Francis (copied) can probably present some of the upfront science, but the final (fundraising) slide is not something he can really talk about. Would you be willing to at least split duties on this with him? I think we'd be happy with whatever division of labor you and Francis would agree to; I know Francis will be talking about ACTIV as well.
>
> I have also attached a brief text description of the project which I will ask the Hever folks to distribute prior to the meeting, if OK with you both. Please let me know any questions or changes you'd like to the slide deck.
>
> Thanks, David
>
> David Wholley
> Senior Vice-President, Research Partnerships
> Foundation for the National Institutes of Health
> (b6 | fnih.org<https://urldefense.proofpoint.com/v2/url?u=http-3A__www.fnih.org&d=DwMFAg&c=UE1eNsedaKnc0OYl_u8bfw&r=LpzurVkxIFHC1R9i_ZaDFfLVDjtkjtCxUNFcuRoHiFI&m=6kyUMfIJPDqSzMmN-DuZxROzHlh_fr_Kz98DVptzzKY&s=yRB0hgdUW3hqNoyUajeOeHtK6Ma_3D9Lq7TswHGVyAY&e=>
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> [cid:image005.png@01D6EAB2.80142350]
>

From: Colvis, Christine (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4B7E84CCE098457896B2DF19FA172C87-CCOLVIS]
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Subject: RE: IP, CDA, FOIA for ACTIV prelinical WG

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My $0.02 inline in red.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, June 10, 2020 11:19 AM
To: Menetski, Joseph (FNIH) [T] < b6
Cc: Colvis, Christine (NIH/NCATS) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6
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Best,
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Ellen L. Gadbois, Ph.D.

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National Institutes of Health
Building 1 Suite 218
voice: b6
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Thanks, Christine. I spoke to Joe and David Wholley about these things yesterday and offered to run drafts of IP policy or CDAs through OGC and/or get an explanation of FOIA for the working group. They basically thought it wasn't necessary at this time. You know better than I exactly what's happening with the working group, so please just feel free to let me know if you think something needs doing and you would like any help on it. Ann Martin is the NIH OGC lead on ACTIV and she's happy to review these sorts of things.

Re. FOIA—I did tell David & Joe that what I generally hear from the FOIA lawyers is that all information held by NIH is subject to FOIA, but when there is a FOIA request, they then look at what can be withheld under the FOIA exemptions (trade secret/commercial confidential info, etc.). So my sense is that we can't make absolute promises up front about what exactly can be withheld, but can point to the exemption categories in the statute. The details are here: https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/freedom-information-act-5-usc-552

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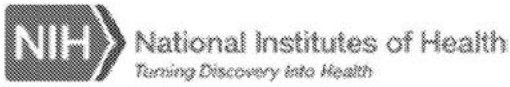
voice: b6
fax: 301-402-0280



From: Martin, Ann (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23B309BDBB1249D99E3AB0A7CD962332-MARTINAD]
Sent: 6/10/2020 4:12:55 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]
Subject: RE: heads up: IP, CDA, FOIA for ACTIV prelinical WG

Ellen, This is very helpful information – much appreciated! -Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, June 10, 2020 11:26 AM
To: Martin, Ann (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6 Tucker, Jessica (NIH/OD) [E] < b6
Subject: heads up: IP, CDA, FOIA for ACTIV prelinical WG

FYI Ann—see below. There are probably more legal agreements to be worked out here: IP, CDAs, and the companies want to know how FOIA applies. Nothing for you to do yet, but wanted to give you a heads up. I think a key question is what, if anything, can be ACTIV-wide, and what needs to be developed specifically for individual ACTIV activities.
Ellen

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, June 10, 2020 11:19 AM
To: Menetski, Joseph (FNIH) [T] < b6
Cc: Colvis, Christine (NIH/NCATS) [E] < b6 Culp, Michelle (NIH/OD) [E] b6
Subject: IP, CDA, FOIA for ACTIV prelinical WG

Hi Joe,

I listened to the ACTIV preclinical working group call just now. I am happy to help coordinate any necessary reviews by the NIH division of the HHS Office of the General Counsel, so please let me know what you think needs doing. NIH OGC is already planning to review the draft ACTIV antitrust policy when I receive that from David.

I imagine you are already thinking this through, but questions that just came to my mind:

1) Should there be a single IP agreement for ACTIV? Or are there enough differences between the working groups that there need to be multiple tailored agreements? Is there something from the Biomarkers Consortium that would be useful here?

2) Just out of curiosity—how is it that the Sanofi rep was the one who wrote a starting IP agreement?
3) Would CDAs need to be specific to individual ACTIV activities/data sets or working groups? NIH should probably see those drafts in case NIH staff would be a party to any of them. I recall an AMP CDA for data being shared with the RA/lupus steering committee, which two NIH ICs signed, so that might be a useful starting point.
4) FOIA...this is certainly for NIH to answer, so if you could come up with the question, I can loop in our FOIA folks. There are FOIA exemptions that are likely relevant here, but I would need an NIH FOIA lawyer to provide the official blurb.

Anyway, let me know what needs doing and I think you should likely check with David and the other FNIH WG co-chairs since these are probably ACTIV-wide issues.

Best,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: **b6**
fax: 301-402-0280

Sent: 6/16/2020 10:41:10 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Mike,

I was confused as well and assumed Amanda would insert information after b5 ' Got it and will relay this message – sorry for bothering you with this but thought it would be useful to follow up on this before the response was provided.

I will recommend providing the response you already shared or not answering this question and if they do not feel comfortable with this, I will recommend they follow up with NIAID who will also likely give the same response.

Thanks and have a good evening,
Ashley

From: Santos, Michael (FNIH) [T] < b6
Sent: Tuesday, June 16, 2020 6:32 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Ashley,

My apologies, I'm slightly confused by:

b5

I'm missing what "that" refers to in "that is our assessment."

30k is the number of participants expected in the efficacy trial, which doesn't answer the question of the number of cases required. That number is about b5 . I don't think that's public information so I would not share it, though I'm not 100% sure that it hasn't been shared. R0 isn't really relevant, but incidence rate is. b5 , but again I'm just sharing that with you for your awareness: I wouldn't share that publicly without confirming it's already been shared.

If Amanda doesn't want to give a non-answer answer, my advice would be to say that we can't answer that question at this time (or whatever the appropriate way of saying that is). But of course this is all up to you.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

---

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 6:23 PM
To: Santos, Michael (FNIH) [T] < b6
Subject: FW: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Mike,

I'm affirming with Amanda that the 3rd response was intentionally drafted to not respond but apparently Dr. Collins has publicly stated a number although I have yet to find this statement. Thoughts on the proposed alternative below?

Thanks,
Ashley

From: Fine, Amanda (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 5:39 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] < b6 Wojtowicz, Emma (NIH/OD) [E] < b6
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Ashley-

We have some concerns about the proposed response to the last question since it doesn't really answer it.

Could we say something along the lines of: b5

Also, we think Dr. Collins might have said a number publicly around 30k?

Thanks again for your help!
Amanda

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 1:45 PM
To: Fine, Amanda (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] b6 >; Wojtowicz, Emma (NIH/OD) [E] < b6
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Amanda,

Please see responses from the ACTIV vaccines working group lead below –I agree with the response to the second bullet you've provided.

- On ACTIV not planning to support human challenge studies, is this a new decision that results from a recent review of the issues surrounding the idea? Or consistent with the position all along, and the issue will be up for discussion going forward even if there's no plan today? The ACTIV Vaccines Working Group reviewed the question of whether controlled human infection models could accelerate COVID-19 vaccine development, and the ACTIV perspective has been submitted for publication.

- Is the expectation of sufficient natural transmission based on new or changing data or trends in terms of infection rates in the U.S.? We are following data being reported across the US and working closely with our colleagues at CDC to track infection rates.

_ Is it possible to estimate what levels of transmission would be required for efficacy studies to be feasible in summer 2020, and what kind of R factor? Or estimate how many expected cases would be needed? b5

b5

Thanks,
Ashley

From: Fine, Amanda (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 1:37 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] < b6 Wojtowicz, Emma (NIH/OD) [E] < b6
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Thank you thank you thank you.

From: Parker, Ashley (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 1:15 PM
To: Fine, Amanda (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] < b6 Wojtowicz, Emma (NIH/OD) [E] < b6
Subject: RE: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Amanda,

Happy to help – I think we want to say that the human challenge trials would take longer than the proposed pathways by ACTIV to use vaccine efficacy data from phase 3 clinical trials to accelerate vaccines. However, this information has been submitted for publication and likely should not be discussed yet – let me confirm with the vaccine WG leads on the estimated timeframe for publication.

Regarding the other 2 bullets which are not ACTIV specific – I would defer to NIAID.

I will get you a response shortly.

Thank you,
Ashley

From: Fine, Amanda (NIH/OD) [E] < b6
Sent: Tuesday, June 16, 2020 12:40 PM
To: Parker, Ashley (NIH/OD) [E] < b6
Cc: Myles, Renate (NIH/OD) [E] < b6 Wojtowicz, Emma (NIH/OD) [E] < b6
Subject: FOR INPUT: Bloomberg request: human challenge trials and Covid

Hi Ashley-

Hope you're doing well. A reporter from Bloomberg reached out to us about human challenge trials for COVID-19 vaccines. We replied with our standard language, but he followed up with the below questions. We drafted some language based on what we think the answers are (in red) for some of the questions, but need someone with expertise to weigh in. Would you be able to review and provide us with input?

Thanks in advance!
Amanda

From: James Paton (BLOOMBERG/ NEWSROOM:) < b6
Sent: Tuesday, June 16, 2020 5:22 AM
To: Fine, Amanda (NIH/OD) [E] < b6
Cc: Wojtowicz, Emma (NIH/OD) [E] < b6 Myles, Renate (NIH/OD) [E] < b6
Subject: RE: human challenge trials and Covid

Hi Amanda, thanks very much. A few more questions:

- On ACTIV not planning to support human challenge studies, is this a new decision that results from a recent review of the issues surrounding the idea? Or consistent with the position all along, and the issue will be up for discussion going forward even if there's no plan today? This has been a consistent position all along. However, since we want to pursue the method that will bring vaccines to market quickly while ensuring safety and efficacy, the working group was tasked to explore whether human challenge trials would be needed to do so.

- Is the expectation of sufficient natural transmission based on new or changing data or trends in terms of infection rates in the U.S.? We are following data being reported across the US and working closely with our colleagues at CDC to track infection rates.

_ Is it possible to estimate what levels of transmission would be required for efficacy studies to be feasible in summer 2020, and what kind of R factor? Or estimate how many expected cases would be needed?

Thanks a lot. Happy to chat too.

James

From: b6 At: 06/15/20 18:24:03
To: James Paton (BLOOMBERG/ NEWSROOM:)
Cc: b6
Subject: RE: human challenge trials and Covid

Hi James-

Thanks for reaching out. See below, attributable to NIH generally:

ACTIV is not planning to support human challenge studies for COVID-19. There is an expectation of sufficient natural transmission for efficacy studies that will be launched in summer 2020. The development of a human challenge model would take longer than this timeline and human challenge studies have a number of serious ethical considerations.

Hope you're staying well,

Amanda

From: James Paton (BLOOMBERG/ NEWSROOM:) <jpaton4@bloomberg.net>
Sent: Monday, June 15, 2020 9:32 AM
To: Fine, Amanda (NIH/OD) [E] < b6 Wojtowicz, Emma (NIH/OD) [E] < b6 Myles, Renate (NIH/OD) [E] < b6
Subject: human challenge trials and Covid

Hi all, I know the director has talked about human challenge studies in recent months and I saw that an NIH working group was set up last month to examine the scientific and practical considerations. Are you able to tell me the status of that, what findings have emerged from the group, what it is studying exactly and when further details will be provided? We're working at a story on the topic.

Thanks very much.

James Paton

James Paton
Health Reporter
Bloomberg News
Office: +44 (0)20 3525 0679
Mobile: b6
Twitter: @JamesPaton14

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/11/2020 6:00:45 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]
Subject: Re: Question from Baric re Major Action at ACTIV

No—I really couldn't tell. The general discussion was broader but including mutants escaping drugs.

Sent from my iPhone

On Nov 11, 2020, at 12:51 PM, Tucker, Jessica (NIH/OD) [E] < b6 wrote:

Thanks. Was it clear what types of mutations he was referencing? That language is limited to drug resistance traits.

From: "Gadbois, Ellen (NIH/OD) [E]" < b6
Date: Wed, Nov 11, 2020, 12:43 PM
To: "Tucker, Jessica (NIH/OD) [E]" < b6
Subject: Re: Question from Baric re Major Action at ACTIV

Thanks. I'll forward whatever else I see about this. I guess I got the person right but policy wrong!

Sent from my iPhone

On Nov 11, 2020, at 12:32 PM, Tucker, Jessica (NIH/OD) [E] < b6 wrote:

Ellen and other OSPers,

Thanks. I'm looping in Carrie and others here, as well, since I initially flagged this possibility a few weeks ago and now it looks like it is moving to another venue involving FC and ACTIV.

Dr. Baric is likely referencing the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section III-A-1, which requires NIH Director approval for the introduction of drug resistance traits to microorganisms not known to acquire the trait naturally, if such ability could compromise the ability to control disease (text copied directly below for reference). We were approached a few weeks ago about a possible request to conduct this work- Dr. Denison (NSABB member) at VUMC and Dr. Baric at UNC are collaborating. Kathryn can provide more details, but I believe that the current situation is that we have asked the institutions to provide some more information so we can ascertain if it is a Major Action under the *NIH Guidelines*, and that conversation with the relevant institutions occurred (I think) on 10/22, and I think we are still awaiting that information. The process would involve us confirming it is a Major Action, posting the proposed work in the Federal Register for a minimum of 15 days for public comment, getting NIH approval or disapproval (and consulting with relevant

internal USG experts throughout), and finally, IBC approval. I believe these steps can happen relatively quickly, as needed, but of course, we need the info from the institutions. Also note that this language is specific to the introduction of drug resistance traits- I'm not sure if Dr. Baric was referencing mutations beyond those. P3CO would depend on whether NIH is funding the work, and that P3CO determination would be at the discretion of the funding agency (e.g., NIAID) to assess and forward to the correct review process, if so. NIAID is well versed in that process.

Kathryn or Marina, please correct me if I have misspoken. Text of the *NIH Guidelines* below for reference.

Section III-A-1. Major Actions under the *NIH Guidelines*

Experiments considered as *Major Actions* as defined in Section III-A-1-a under the *NIH Guidelines* cannot be initiated without submission of relevant information on the proposed experiment to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov, the publication of the proposal in the *Federal Register* for a minimum of 15 days of comment, and specific approval by NIH. The containment conditions or stipulation requirements for such experiments will be set by NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D, *Major Actions Taken under the NIH Guidelines*.

Section III-A-1-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, *Footnotes and References of Sections I-IV*), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will require NIH Director approval.

Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH OSP will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III-A-1-a and therefore requires NIH Director approval. An Institutional Biosafety Committee may also consult with NIH OSP regarding experiments that do not meet the requirements of Section III-A-1-a but nonetheless raise important public health issues.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, November 11, 2020 11:31 AM
To: Culp, Michelle (NIH/OD) [E] < b6 Tucker, Jessica (NIH/OD) [E] < b6 Harris, Kathryn (NIH/OD) [C] < b6 Jorgenson, Lyric (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: HHS P3CO Framework

b5

b5

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, November 11, 2020 11:18 AM
To: Menetski, Joseph (FNIH) [T] b6 ; Colvis, Christine (NIH/NCATS) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 >; Jessica (NIH/OD) Tucker [E] b6) b6 ; Harris, Kathryn (NIH/OD) [C] < b6 >; Jorgenson, Lyric (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] < b6 >
Subject: HHS P3CO Framework

Hi Joe & Christine,

I think Ralph Baric was probably referring to the "P3CO Framework" on the ACTIV preclinical working group call today. The policy is here: https://www.phe.gov/s3/dualuse/Documents/p3co.pdf and there's some explanation at https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research.
My supervisor, Jessica Tucker, was involved in the development of the policy. She's on leave for the rest of the week so I am cc'ing others in OSP. Once Ralph writes up a description of the issues regarding his research, I'm sure OSP would be happy to look into this. I think there have been a lot of other biosecurity questions coming in from COVID researchers.

Best,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

<image001.png>

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/13/2020 7:43:37 PM
To: Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]
Subject: RE: Question from Baric re Major Action at ACTIV

FYI the same ACTIV group has a Zoom scheduled for 10 a.m. on Nov 18 to discuss: "Subgroup discussion of prediction of therapy resistance from emerging viral sequence data."

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, November 11, 2020 1:02 PM
To: Tucker, Jessica (NIH/OD) [E] < b6
Subject: Re: Question from Baric re Major Action at ACTIV

I already told Joe I might have flagged the wrong policy but that OSP could sort it out either way once Ralph sent the details.

Sent from my iPhone

> On Nov 11, 2020, at 12:52 PM, Tucker, Jessica (NIH/OD) [E] < b6 wrote:
>
> Oh, and let me know if you think I (or you) should say something directly to FNIH or just hold.
>
> ---
>
> **From:** "Gadbois, Ellen (NIH/OD) [E]" < b6 >
> **Date:** Wed, Nov 11, 2020, 12:43 PM
> **To:** "Tucker, Jessica (NIH/OD) [E]" b6
> **Subject:** Re: Question from Baric re Major Action at ACTIV
>
> Thanks. I'll forward whatever else I see about this. I guess I got the person right but policy wrong!
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> Sent from my iPhone
>
> > On Nov 11, 2020, at 12:32 PM, Tucker, Jessica (NIH/OD) [E] b6 wrote:
> >
> > Ellen and other OSPers,
> >
> > Thanks. I'm looping in Carrie and others here, as well, since I initially flagged this possibility a few weeks ago and now it looks like it is moving to another venue involving FC and ACTIV.
> >
> > Dr. Baric is likely referencing the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section III-A-1, which requires NIH Director approval for the introduction of drug resistance traits to microorganisms not known to acquire the trait naturally, if such ability could compromise the ability to control disease (text copied directly below for reference). We were approached a few weeks ago about a possible request to conduct this work- Dr. Denison (NSABB member) at VUMC and Dr.

Baric at UNC are collaborating. Kathryn can provide more details, but I believe that the current situation is that we have asked the institutions to provide some more information so we can ascertain if it is a Major Action under the *NIH Guidelines*, and that conversation with the relevant institutions occurred (I think) on 10/22, and I think we are still awaiting that information. The process would involve us confirming it is a Major Action, posting the proposed work in the Federal Register for a minimum of 15 days for public comment, getting NIH approval or disapproval (and consulting with relevant internal USG experts throughout), and finally, IBC approval. I believe these steps can happen relatively quickly, as needed, but of course, we need the info from the institutions. Also note that this language is specific to the introduction of drug resistance traits- I'm not sure if Dr. Baric was referencing mutations beyond those. P3CO would depend on whether NIH is funding the work, and that P3CO determination would be at the discretion of the funding agency (e.g., NIAID) to assess and forward to the correct review process, if so. NIAID is well versed in that process.

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From: Gadbois, Ellen (NIH/OD) [E] b6 v>
Sent: Wednesday, November 11, 2020 11:31 AM
To: Culp, Michelle (NIH/OD) [E] b6 ; Tucker, Jessica (NIH/OD) [E] b6 ; Harris, Kathryn (NIH/OD) [C] b6 ; Jorgenson, Lyric (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: HHS P3CO Framework

b5

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Wednesday, November 11, 2020 11:18 AM
To: Menetski, Joseph (FNIH) [T] b6 ; Colvis, Christine (NIH/NCATS) [E] b6 v>
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Jessica (NIH/OD) Tucker [E] (b6 b6 ; Harris, Kathryn (NIH/OD) [C] b6 >; Jorgenson, Lyric (NIH/OD) [E] < b6 ; Parker, Ashley (NIH/OD) [E] b6
Subject: HHS P3CO Framework

Hi Joe & Christine,

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My supervisor, Jessica Tucker, was involved in the development of the policy. She's on leave for the rest of the week so I am cc'ing others in OSP. Once Ralph writes up a description of the issues regarding his research, I'm sure OSP would be happy to look into this. I think there have been a lot of other biosecurity questions coming in from COVID researchers.

Best,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

<image001.png>

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/11/2020 5:48:57 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]
Subject: Re: HHS P3CO Framework

Actually it may be a different policy that's applicable, but either way my office can look into it once we get the details.

Sent from my iPhone

On Nov 11, 2020, at 11:24 AM, Menetski, Joseph (FNIH) [T] < b6 wrote:

Thank you Ellen. I had no idea what he was talking about, so I am glad you were there.

It was also why I asked him to write something down for me. I knew I would not be able to capture his issue.

I will make sure to get his note to you when I send it to David and Maria for the war room.

Joe

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, November 11, 2020 11:18 AM
To: Menetski, Joseph (FNIH) [T] < b6 Colvis, Christine (NIH/NCATS) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Tucker, Jessica (NIH/OD) [E] < b6 Harris, Kathryn (NIH/OD) [C] < b6 Jorgenson, Lyric (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: HHS P3CO Framework

Hi Joe & Christine,

I think Ralph Baric was probably referring to the "P3CO Framework" on the ACTIV preclinical working group call today. The policy is here: https://www.phe.gov/s3/dualuse/Documents/p3co.pdf and there's some explanation at https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research.
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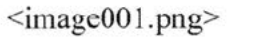
Best,
Ellen

Ellen L. Gadbois, Ph.D.

Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: **b6**
fax: 301-402-0280



From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/11/2020 4:35:58 PM
To: O'Reilly, Marina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym]; Ramkissoon, Kevin (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7cce7b0fb85a40f3b4dee4e68fc5d5cc-ramkissoonk]
CC: Jessica (NIH/OD) Tucker [E] (b6 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]; Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]
Subject: FW: HHS P3CO Framework

Should have copied you two also...nothing to do right now until we see more.

From: Menetski, Joseph (FNIH) [T] < b6
Sent: Wednesday, November 11, 2020 11:25 AM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Colvis, Christine (NIH/NCATS) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6 Tucker, Jessica (NIH/OD) [E] < b6 Harris, Kathryn (NIH/OD) [C] < b6 Jorgenson, Lyric (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: HHS P3CO Framework

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I will make sure to get his note to you when I send it to David and Maria for the war room.

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Sent: 11/13/2020 2:27:53 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: HHS P3CO Framework

Sure. I have a conflict with the FNIH Deloitte call today, but if Ralph's comment comes up, feel free to tell them that once Joe gets a description from Baric of the issue, we'll pass that on to the people in OSP who know how to handle it. (And from what Jessica wrote, it sounds like she probably already knows what this is about and OSP is waiting for information from the institutions--so we are not the hold-up.)

From: Culp, Michelle (NIH/OD) [E] < b6
Sent: Thursday, November 12, 2020 5:42 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Subject: RE: HHS P3CO Framework

Ellen,
Thanks for keeping me in the loop. This is all new info for me.
-Michelle

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, November 11, 2020 11:31 AM
To: Culp, Michelle (NIH/OD) [E] b6 >; Tucker, Jessica (NIH/OD) [E] b6 Harris, Kathryn (NIH/OD) [C] b6 >; Jorgenson, Lyric (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E] < b6
Subject: RE: HHS P3CO Framework

b5

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Cc: Culp, Michelle (NIH/OD) [E] b6 Jessica (NIH/OD) Tucker [E] b6 < b6 Harris, Kathryn (NIH/OD) [C] b6 >; Jorgenson, Lyric (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E] < b6
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Sent: 11/11/2020 4:26:12 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Tucker, Jessica (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]; Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: HHS P3CO Framework

Sounds good—thanks.

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Sent: 11/17/2020 8:58:25 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: O'Reilly, Marina (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d6c68e99e94ea6bc7872cfbf0d0176-oreillym]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Harris, Kathryn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79d72a4a3dcb43e785c83411756cd9e7-HarrisKath]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]
Subject: UPDATE FOR CW: Question from Baric re Major Action and ACTIV

Carrie,

Just to update you on this thread, Kathryn and I spoke with Joe Menetski from FNIH late yesterday (and Michelle, thanks for listening in). It sounds like the issue here is that FC has indicated an interest in predicting the effect of emerging viral mutations on resistance to therapies and vaccines that are under development, and the group is discussing what barriers might exist for doing some relevant work to introduce mutations into SARS-CoV-2. Ralph Baric mentioned the Major Action language in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* as a potential barrier to fast work on these questions. Kathryn and I explained to Joe that the Major Action language is quite circumscribed- it is the deliberate transfer of a therapeutically useful drug resistance trait. Of course, the devil is in the details, but I think Joe generally understands the situation. This may well continue to come up in ACTIV discussions with FC and FNIH, so I just wanted you to be aware. I will continue to keep you in the loop as more develops, since Joe told us he would likely come back to us to discuss further.

Best,

Jessica

From: Tucker, Jessica (NIH/OD) [E]
Sent: Wednesday, November 11, 2020 12:32 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6 Culp, Michelle (NIH/OD) [E] < b6 Harris, Kathryn (NIH/OD) [C] < b6 Jorgenson, Lyric (NIH/OD) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6
Cc: Wolinetz, Carrie (NIH/OD) [E] < b6 O'Reilly, Marina (NIH/OD) [E] < b6 Ramkissoon, Kevin (NIH/OD) [C] < b6
Subject: Question from Baric re Major Action at ACTIV

Ellen and other OSPers,

Thanks. I'm looping in Carrie and others here, as well, since I initially flagged this possibility a few weeks ago and now it looks like it is moving to another venue involving FC and ACTIV.

Dr. Baric is likely referencing the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section III-A-1, which requires NIH Director approval for the introduction of drug resistance traits to microorganisms not known to acquire the trait naturally, if such ability could compromise the ability to control disease (text copied directly below for reference). We were approached a few weeks ago about a possible request to conduct this work- Dr. Denison (NSABB member) at VUMC and Dr. Baric at UNC are collaborating. Kathryn can provide more details, but I believe that the current situation is that we have asked the institutions to provide some more information so we can ascertain if it is a Major Action under the *NIH Guidelines*, and that conversation with the relevant institutions occurred (I think) on 10/22, and I think we are still awaiting that information. The process would involve us confirming it is a Major Action, posting the proposed work in the Federal Register for a minimum of 15 days for public comment, getting NIH approval or disapproval (and consulting with relevant internal USG experts throughout), and finally, IBC approval. I believe these steps can happen relatively quickly, as needed, but of course, we need the info from the institutions. Also note that this language is specific to the introduction of drug resistance traits- I'm not sure if Dr. Baric was referencing mutations beyond those. P3CO would depend on whether NIH is funding the work, and that P3CO determination would be at the discretion of the funding agency (e.g., NIAID) to assess and forward to the correct review process, if so. NIAID is well versed in that process.

Kathryn or Marina, please correct me if I have misspoken. Text of the *NIH Guidelines* below for reference.

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Consideration should be given as to whether the drug resistance trait to be used in the experiment would render that microorganism resistant to the primary drug available to and/or indicated for certain populations, for example children or pregnant women.

At the request of an Institutional Biosafety Committee, NIH OSP will make a determination regarding whether a specific experiment involving the deliberate transfer of a drug resistance trait falls under Section III-A-1-a and therefore requires NIH Director approval. An Institutional Biosafety Committee may also consult with NIH OSP regarding experiments that do not meet the requirements of Section III-A-1-a but nonetheless raise important public health issues.

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NIH National Institutes of Health
Turning Discovery into Health

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Sent: 11/11/2020 6:07:24 PM
To: Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]
Subject: RE: Question from Baric re Major Action at ACTIV

Thanks. Kind of annoying, since we are waiting on THEM... not the other way around.

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Wednesday, November 11, 2020 1:02 PM
To: Tucker, Jessica (NIH/OD) [E] < b6
Subject: Re: Question from Baric re Major Action at ACTIV

I already told Joe I might have flagged the wrong policy but that OSP could sort it out either way once Ralph sent the details.

Sent from my iPhone

> On Nov 11, 2020, at 12:52 PM, Tucker, Jessica (NIH/OD) [E] < b6 wrote:
>
> Oh, and let me know if you think I (or you) should say something directly to FNIH or just hold.
>
> **From:** "Gadbois, Ellen (NIH/OD) [E]" b6 >
> **Date:** Wed, Nov 11, 2020, 12:43 PM
> **To:** "Tucker, Jessica (NIH/OD) [E]" b6
> **Subject:** Re: Question from Baric re Major Action at ACTIV
>
> Thanks. I'll forward whatever else I see about this. I guess I got the person right but policy wrong!
>
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Hi Joe & Christine,

I think Ralph Baric was probably referring to the "P3CO Framework" on the ACTIV preclinical working group call today. The policy is here: https://www.phe.gov/s3/dualuse/Documents/p3co.pdf and there's some explanation at https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-lifts-funding-pause-gain-function-research.
My supervisor, Jessica Tucker, was involved in the development of the policy. She's on leave for the rest of the week so I am cc'ing others in OSP. Once Ralph writes up a description of the issues regarding his research, I'm sure OSP would be happy to look into this. I think there have been a lot of other biosecurity questions coming in from COVID researchers.

Best,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

<image001.png>

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 11/2/2020 9:42:44 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse b6 Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan b6 asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: ACTIV EC & WG Co-chair Pre-call
Attachments: 11.4 ACTIV Executive Committee Meeting 20201102_v4.pptx

-----Original Appointment-----
From: Melencio, Cheryl (FNIH) [T] < b6
Sent: Friday, September 25, 2020 11:27 AM
To: Melencio, Cheryl (FNIH) [T]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 5/19/2020 9:35:00 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Re: Meet to discus new liaison roles

Got it, thanks

Sent from my iPhone

On May 19, 2020, at 5:30 PM, Wholley, David (FNIH) [T] < b6 wrote:

See in italics below

From: Gadbois, Ellen (NIH/OD) [E] < b6
Sent: Tuesday, May 19, 2020 3:51 PM
To: Wholley, David (FNIH) [T] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: Meet to discus new liaison roles

Hi again David,

I'm dropping off LT so he doesn't have to read extra emails. Michelle and I spoke briefly this morning and came up with some basic questions. A few of these (especially what Michelle and I will be doing) are probably better suited for our call tomorrow, but if there are quick/easy answers that you could give now, that might help us use our time with Dr. Tabak better.

Thanks,
Ellen & Michelle

- Flow of funds:
  - b4
  - Are NIH intramural researchers carrying out any ACTIV activities? *Not that I am aware of.*

- Agreements:
  - Are there any written agreements to which NIH is a party? *We have an OT agreement with NIH OD to perform the design work for ACTIV.*

- Have any governance provisions been developed? *FNIH is working on an antitrust policy but otherwise no.*
- What master trial agreements will be needed, are in development and deployed? *To discuss with Larry.*

- Roles & Responsibility
  - What are the main gaps in coordination that you would like filled? *To discuss with Larry.*
  - To whom are WGs accountable? *The ACTIV Executive Committee.*
  - Is FNIH serving as the group to provide overall coordination of all ACTIV activities? Is Deloitte providing support for this coordination? *Yes, and yes.*
  - Is there be a hub for communication? For example, website, SharePoint or other system to support a document library and communication updates? *We have a Basecamp site we are using for sharing among the WG members and NIH OD has developed and just released a website.*
  - Is NCATS providing the central data and clinical operations coordination for study implementation? *No.*

From: Wholley, David (FNIH) [T] b6
Sent: Monday, May 18, 2020 4:43 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Melencio, Cheryl (FNIH) [T] b6 ; Tabak, Lawrence (NIH/OD) [E] <b
Subject: RE: Meet to discus new liaison roles

We can wait till our orientation but one thing we will want to discuss is what meetings you want to/should attend.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, May 18, 2020 3:54 PM
To: Wholley, David (FNIH) [T] b6
Cc: Culp, Michelle (NIH/OD) [E] b6 ; Melencio, Cheryl (FNIH) [T] b6
Subject: RE: Meet to discus new liaison roles

That's very helpful—thanks.

From: Wholley, David (FNIH) [T] b6
Sent: Monday, May 18, 2020 2:05 PM
To: Gadbois, Ellen (NIH/OD) [E] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Melencio, Cheryl (FNIH) [T] b6
Subject: RE: Meet to discus new liaison roles

Sure. I've been so busy I forgot to send the materials. Here are slides from our last several meetings. The "daily update" includes some of the near term meetings; Cheryl can give the schedule for the others. I have also attached the full rosters for the working groups. Cheryl, can you also please send the list of the FNIH/Deloitte support team members? Thanks

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Monday, May 18, 2020 1:36 PM
To: Wholley, David (FNIH) [T] < b6
Cc: Culp, Michelle (NIH/OD) [E] < b6
Subject: RE: Meet to discus new liaison roles

Hi David,
I hope that you and your family is well.
I'm just checking to see if there are any materials ready for Michelle and me to review before Wednesday. I'm particularly interested in what the schedule looks like for the various working groups. I am not totally sure what I'll be doing as part of this, but it would be good to know about any key dates.
Thanks very much,
Ellen

From: Wholley, David (FNIH) [T] < b6
Sent: Wednesday, May 13, 2020 2:28 PM
To: Tabak, Lawrence (NIH/OD) [E] b6 >
Cc: Culp, Michelle (NIH/OD) [E] b6 Gadbois, Ellen (NIH/OD) [E] b6 >; Burrus-Shaw, Cyndi (NIH/OD) [E] b6 >; Simon, Dina (NIH/OD) [C] b6 Adam, Stacey (FNIH) [T] b6 >; Santos, Michael (FNIH) [T] b6 Menetski, Joseph (FNIH) [T] < b6 ; Tountas, Karen (FNIH) [T] b6 >; Freire, Maria (FNIH) [T] b6 James, Stephanie (FNIH) [T] < b6
Subject: RE: Meet to discus new liaison roles

Excellent news, Larry! Welcome aboard to Michelle and Ellen. I think it would make sense for us to include my four key project leads: Stacey Adam, Joe Menetski, Karen Tountas, and Mike Santos on the call so we can hit the ground running. OK for me to send ahead some materials, like the slides and notes from the last LT meeting, to assist in getting them oriented? Or are you sharing info with them in advance of the call? Cheryl Melencio can arrange schedules on our end.

Many thanks,
David

From: Tabak, Lawrence (NIH/OD) [E] b6
Sent: Wednesday, May 13, 2020 1:31 PM
To: Wholley, David (FNIH) [T] < b6
Cc: Culp, Michelle (NIH/OD) [E] b6 >; Gadbois, Ellen (NIH/OD) [E] b6 ; Burrus-Shaw, Cyndi (NIH/OD) [E] b6 Simon, Dina (NIH/OD) [C] b6
Subject: Meet to discus new liaison roles

David,

As you discussed with Francis, Michelle Culp and Ellen Gadbois stand ready to assist with enhancing communications/actions between NIH and FNIH for the ACTIV program. Francis, Carrie, and I have discussed, and for the purpose of this activity Michelle and Ellen will use me as their point of contact at NIH.

I would appreciate holding an initial meeting for the three of us with you and any other members of your team you wish to include to scope out initial activities etc. A member of my team will reach out to set up a time.

Best wishes,
Larry

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 6/24/2020 1:50:07 AM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: ORD COVID-19 Update June 23, 2020
Attachments: ORD COVID-19 Update June 23, 2020.pdf

FYI.

From: Wholley, David (FNIH) [T] b6
Sent: Tuesday, June 23, 2020 7:31 PM
To: Collins, Francis (NIH/OD) [E] < b6 Tabak, Lawrence (NIH/OD) [E] < b6 Austin, Christopher (NIH/NCATS) [E] < b6 Freire, Maria (FNIH) [T] < b6 Lane, Cliff (NIH/NIAID) [E] < b6 Parker, Ashley (NIH/OD) [E] < b6 Anderson, James (NIH/OD) [E] < b6
Subject: FW: ORD COVID-19 Update June 23, 2020

Fyi, thought we could all use a little uplift.

From: Tountas, Karen (FNIH) [T] b6
Sent: Tuesday, June 23, 2020 6:12 PM
To: Adam, Stacey (FNIH) [T] b6 James, Stephanie (FNIH) [T] b6 >; Menetski, Joseph (FNIH) [T] b6 Santos, Michael (FNIH) [T] < b6 Wholley, David (FNIH) [T] b6
Subject: FW: ORD COVID-19 Update June 23, 2020

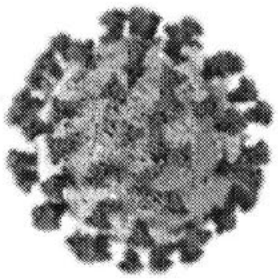
The VA and ACTIV, just an FYI…

From: Davey, Victoria < b6
Sent: Tuesday, June 23, 2020 10:14 AM
To: Tountas, Karen (FNIH) [T] b6
Subject: FW: ORD COVID-19 Update June 23, 2020

Thought you might like to see one way we in VA keep researchers and others abreast of ACTIV in our weekly COVID-19 research newsletter.

From: ORDCOVID19 <ORDCOVID19@va.gov>
Sent: Tuesday, June 23, 2020 9:36 AM
To: VHA CO 10X2 ACOS <VHACO10X2ACOS2@va.gov>; VHA CO 10X2 AO <VHACO10X2AO2@va.gov>
Cc: ORDCOVID19 <ORDCOVID19@va.gov>
Subject: ORD COVID-19 Update June 23, 2020

ORD COVID-19 UPDATE



June 23, 2020

In This Issue

Message from the CRADO

Dear VA research colleagues,

Our mission as a VA research community is clear: to improve the well-being of Veterans and the nation through research. In the era of COVID-19, one of the ways that we do that is by giving our Veterans access to high-quality clinical trials of promising vaccines and therapeutics. Since the outset of the pandemic, we've been in conversations with numerous federal and industry partners. They have recognized VA as a vital partner in our country's response to COVID-19, given our community of talented researchers, our diverse and vulnerable population, and our size. I am excited to share more news with you, so in the coming weeks, you can expect to hear about several new SARS-CoV-2/COVID-19 vaccine and therapeutics trials being launched at VA medical centers. Some initial details on the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and Operation Warp Speed (OWS) initiatives are provided below.

The tools to defeat SARS-CoV-2/COVID-19 will have started as ideas, which researchers codify in proposals and protocols. Peer review is an essential ingredient in the process of getting these ideas funded. During routine times, the various services within ORD each hold two scientific review board meetings per year. These meetings involve teams of dedicated and conscientious reviewers who spend many hours reviewing and discussing investigator proposals to determine which are the most deserving of support. While peer review is generally considered part of one's responsibility to the academic community, the time spent in this endeavor is not directly

compensated, and often comes on top of what is already a packed clinical, research, and teaching schedule.

With the urgency of COVID-19, these demands have only increased. In addition to their participation in regular committees, many of our reviewers are being asked to serve on multiple COVID-19 committees and working groups, on behalf of VA and other institutions.

Some of these reviewers are VA employees, and others are not. Some may hold affiliations only with a university, or with an organization such as the National Institutes of Health. But all of ORD's scientific peer reviewers share this in common: an unshakeable commitment to rigorous review; scientific and ethical integrity; and of course, our Veterans.

As we enter week 15 of the pandemic, I want our scientific peer reviewers to know how much I appreciate their efforts. These women and men have generously given their time and expertise so that we can be good stewards of the taxpayer dollars that have been given to us to fulfill our mission.

I hope that each one of you has a safe and fulfilling week.

With gratitude,
Rachel

Rachel Ramoni, DMD, ScD
Chief Research and Development Officer (10X2)
Department of Veterans Affairs

Mayo Clinic Convalescent Plasma Expanded Access Program (EAP)—ORPP&E's FAQs on this program are on the ORD COVID-19 SharePoint. Information about the Mayo Clinic EAP is located here. The Mayo Clinic has issued a safety report assessing the seven days following transfusion for 20,000 hospitalized patients in the Mayo Clinic EAP between April 3 and June 11, 2020, who were deemed at risk of progressing to a severe or life-threatening condition. Highlights of the safety report include that (a) seven-day mortality rates declined to 8.6 %, compared with 12% in a previous safety study of the first 5,000 transfused patients; (b) the recruitment of a diverse population has improved over the course of the Mayo Clinic EAP: Nearly 40% of study participants were women; 20% African Americans; nearly 35% were Hispanic, and nearly 5% Asian; and (c) reports of serious adverse events related to transfusion of the plasma are at under 1%. It is important to reinforce that the analyses were not designed to evaluate the efficacy of convalescent plasma. Information about the Mayo Clinic EAP safety report is located here.

ORD is also reinforcing that the Mayo Clinic has posted an amendment (Protocol Appendix 1) proposing to create a control group for efficacy analysis. VA sites are not authorized at the present time to participate in a creation of a control group for Efficacy Analysis as described in

Protocol Appendix 1. The proposed efficacy analysis are activities outside the scope of the IRB reliance agreement executed between the Mayo Clinic IRB and the VHA Office of Research and Development.

Remote monitoring—ORD issued guidance on June 18 titled "ORD Guidance on Remote Monitoring of VA Clinical Trials by External Monitors Using the Webex Collaboration Technology Sharing Platform." This guidance document located on the ORD Policies and Guidance webpage is an implementation guide for the use of WebEx to conduct remote monitoring for clinical trial monitoring by external monitors (non-VA employees) requiring access to protected health information and the electronic health record (EHR) using a VA employee as the driver of the documents. There are other types of VA-approved collaboration conference sharing platforms that could be used to conduct remote monitoring, including Skype and Microsoft Teams, which are addressed in the ORD guidance document. Please note that ORD is not presenting a position that all monitoring for clinical trial monitoring must be conducted remotely.

ORD also conducted a seminar to discuss the ORD guidance, titled "Facilitating Conduct of Remote Monitoring for Clinical Trials: Key Considerations for VA Researchers," on June 18. The slides and handouts are on ORPP&E's cyberseminar webpage.

ORPP&E toolkits—ORPP&E has published a toolkit for exempt research. Toolkits are resources on specific research-related topics with links to FAQs, flow charts, guidance documents, memorandums, templates, and webinars to make it easier to find information on a specific topic. The exempt toolkit is the first toolkit ORPP&E has published. New toolkits will be published as they are made available. The toolkits are located at on the ORPP&E education webpage.

Animal Research

New FAQ—A new FAQ has been added to the ORD COVID-19 FAQs v3.2 found on SharePoint and can also be found in resources in the "COVID-19 and VA Animal Care and Use Programs" section of the VA Research website. This FAQ is shared below. In addition to FAQs, ORD released a May 26 guidance memo on resuming full experimental support activities in animal facilities. If the memo and FAQ document do not resolve problems, or you have an emergency issue, call Mike Fallon, CVMO, at b6 If there are less pressing concerns regarding the management of animals during this period, email Michael Fallon b6 Alice Huang b6 and Joan Richerson b6).

Do each of my protocols have to be reviewed and approved for restart by the Subcommittee on Research Safety (SRS) and Institutional Animal Care and Use Committee (IACUC)?

The Administrative Hold was NOT placed on Animal and Lab research. We recommend that each facility develop a plan that is vetted by the IACUC and SRS to ensure that there is continuity and consensus in the process of ramping research at your facility. However, if your institution formally placed a hold on IACUC and/or SRS protocols then each protocol that was placed on administrative hold should be reviewed by the committee for restart.

Field Operations

Acknowledgement of VA employment and research support in publications—ORD reminds investigators to make sure your publications relating to COVID-19—or any research topic—include your VA title and the appropriate statements to acknowledge direct or indirect VA research support (see VHA Directive 1200.19 for details). Your adherence to this requirement helps ensure that the VA research program is credited accurately and appropriately in the medical literature and in media reports.

COVID-19 Field Ops group updates—Each Monday a group of field operations representatives meet with ORD representatives to review open major issues from the field perspective. Many of the discussions have evolved into FAQ responses and informed research administration processes. Among the issues covered are personnel, budget, and timekeeping. If you have issues you would like this group to discuss, please send them to the ORDCOVID19 mailbox (ORDCOVID19@va.gov).

Research Activities

New Research Opportunities

Below are updates on various opportunities for VA investigators related to COVID-19. All ORD funding decisions are being highly coordinated across research efforts. Any multisite study that gets funded by ORD in response to the COVID-19 RFAs will be supported by the Central IRB.

Vaccine trials coordinated by ORD are coming!—ORD is participating in the federally organized Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and Operation Warp Speed (OWS) initiatives. Accordingly, ORD is coordinating VA's involvement in national multi-site clinical trials with multiple entities including ACTIV/OWS leads, NIH institutes, companies, contract research organizations, and others as part of larger efforts within a national clinical trials plan. ORD worked with these groups to put forth sites for a vaccine trial scheduled to start in July, with others to follow. More sites for subsequent vaccine trials will be needed. If your site has been contacted directly by a company and/or a or a clinical research organization regarding interest in a vaccine clinical trial for COVID-19, please inform ORDCOVID19@va.gov if you had not already heard from ORD's Partnered Research Program prior to the contact.

ACTIV-2 and ACTIV-3 studies in development—These are national multicenter trials of neutralizing monoclonal antibodies for outpatients and inpatients. VA sites will be solicited soon.

ACTIV site survey—All VA research sites with interest in COVID-19 studies should respond to the ACTIV site survey if they have not done so. ORD is working with NIH on this public-private

partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising vaccines and treatments. Completing a survey on behalf of your site helps determine which research protocols might be best-suited for VA.

Service-specific updates

Clinical Science R&D

CSR&D has issued intent-to-fund notifications for five projects in the second round of review for its Rapid Response Supplement opportunity. The projects are listed on SharePoint.

CSR&D will only have one more round for the June 30 deadline, with awards to be announced by July 30. At this point, CSR&D has far exceeded the investment initially planned for these supplements, and can only consider submissions that are unique contributions (compared with the ongoing research portfolio) and of immediate interest, with a direct focus on screening, diagnosis, or treatment questions.

Investigators should understand this round of review will be highly competitive related to availability of funds. It may be the case that no projects are selected. Applications on topics already covered in funded COVID-19 projects will not be accepted for review. Clinical trials and topics related to investigations of longer-term downstream impacts will not be accepted. CSR&D is now encouraging investigators to make use of standing funding opportunities for any other application focused on COVID-19, such as the CSR&D Fall 2020 Merit Review RFAs. PIs may reach out to our scientific portfolio managers to ask about interest in specific ideas they would like to propose. The announcement has been updated accordingly.

Rehabilitation R&D

Rehabilitation R&D has announced a Special Emphasis Area in its Summer Merit Review RFA/FOA. The emphasis is on physical, cognitive, and psychosocial disability and rehabilitation approaches following COVID-19 infection or social distancing. Check the RR&D intranet site for further information.

Health Services R&D

COVID-19 Rapid Response RFA – Notices of review outcomes (intent to fund) for projects selected for funding in Round 2 were sent to stations on June 12 and have been posted SharePoint. Due to the volume of proposals, number of funded project and budget constraints, we are suspending Round 3 and are suggesting that investigators pursue standard funding vehicles. We remain interested in larger long-term studies of the effects of COVID-19 on care and outcomes for non-COVID-19 disease (acute and chronic) and on long-term care and outcomes of infected patients.

Collaboratory—HSR&D is coordinating work on observational studies using EHR data to examine safety and effectiveness through a Medication Collaboratory, working with FDA and PBM. Initial topics underway are anticoagulants and remdesivir. As new topics are identified there may be additional opportunities for investigators to get involved.

General

Mobile phlebotomy contract—ORD has procured a contract for mobile phlebotomy services to help support COVID-19 research protocols that are funded and/or supported by VA. More details about scope of services and how to access this contract will be shared soon. If you have an immediate need (action needed within 10 days), please email ORDCOVID19@va.gov with the subject line "Mobile Phlebotomy."

Expert reviewers needed—ORD has an urgent need for expert reviewers across many medical specialties related to COVID-19 for the applications that need to be reviewed to set up this new research portfolio. We seek suggestions from the VA research community for expert reviewers we might be able to contact for this reason—particularly in cardiology, infectious disease, pulmonology, data science, and all of the other health-related areas impacted by COVID-19. Please email suggestions to: VHABLRD-CSRD@va.gov.

Biorepositories—An ORD working group has been developing a plan for a VA COVID-19 Biorepository System, funded and supported by ORD, which will be capable of state-of-the art specimen storage, management, and distribution for research purposes. A recent webinar on the topic can be found here. The group, in conjunction with ORD staff, is working with VHA national laboratory leaders to preserve remainder clinical specimens from COVID-19-infected patients, develop a biorepository system or network, and operationalize an oversight board that will manage the sample collection, storage, and review requests to use the samples for research projects.

To support these efforts, please respond to these calls:

- If your facility has capacity to serve as a central biorepository, or one of a small network of VA COVID-19 biorepositories, please let us know at ORDCOVID19@va.gov (include 'Biorepository' in the subject line).
- If you are interested in serving on the oversight board, let us know at ORDCOVID19@va.gov (include 'Biorepository Oversight Board' in the subject line).
- Please report any established or planned biorepository with biospecimens from COVID-19 at https://dvagov.sharepoint.com/sites/vacovhacomm/ORD_Surveys.

On a related note, for general information regarding VA biospecimens in research, please visit www.research.va.gov/programs/tissue_banking.

Industry clinical trials—Through the new ORD Partnered Research Program, VA continues to discuss a number of multi-site clinical trials opportunities with various industry sponsors. Some studies are expected to start soon and others are in the pipeline with central non-disclosure agreements signed. Some recent trials of note include:

- A Phase 3 Open-label, Randomized, Controlled Study to Evaluate the Efficacy and Safety of Intravenously Administered Ravulizumab Compared with Best Supportive Care in Patients

with COVID-19 Severe Pneumonia, Acute Lung Injury, or Acute Respiratory Distress Syndrome (Sponsor: Alexion Pharmaceuticals; NCT04369469)

- A Randomized, Double-Blind, Placebo Controlled, Trial to Evaluate the Efficacy and Safety of Nitazoxanide (NTZ) for Post- Exposure Prophylaxis of COVID 19 and other Viral Respiratory Illnesses in Elderly Residents of Long Term Care Facilities (LTCF) (Sponsor: Romark Medical Institute; NCT04343248)

The VA COVID-19 Cohort Master File (a case list of all positives and negatives tested, updated regularly) has been distributed by the VA National Surveillance Team to the VA Informatics and Computing Infrastructure (VINCI) environment and is now available for use by VA researchers. The same file has also been distributed to Oak Ridge National Laboratory, part of the Department of Energy, to support collaborative VA-DOE research. (To learn more, visit the archived April 22 webinar on the HSR&D website.)

All standing funding mechanisms in ORD, as appropriate, may also be used to propose research relevant to COVID-19.

Note: **To help support the use of convalescent plasma as an investigational treatment,** please encourage those you know who have had a lab diagnosis of COVID-19 and have been symptom-free for 28 days to consider donating blood plasma at an AABB-certified lab. See https://covidplasma.org/ for more information.

Ongoing Research Activities

Below are examples of VA research on COVID-19 that is currently underway.

VA is collaborating with the Department of Defense on an observational, natural history study of COVID-19 illness. This study, CSP #2028—"Epidemiology, Immunology and Clinical Characteristics of COVID-19 (EPIC3)"—will be coordinated by the Cooperative Studies Program and obtained VA Central IRB. The study will be seeking additional VA sites after initial site activities are finalized following a launch at the vanguard sites.

VA sites are taking part in a National Institute of Allergy and Infectious Disease (NIAID)-sponsored adaptive, randomized, placebo-controlled study of the antiviral drug remdesivir plus the anti-inflammatory drug baricitinib for hospitalized patients with COVID-19. VA sites currently include Palo Alto, Denver, New Orleans, and Atlanta. The trial is expected to be active at some 100 U.S. and international sites and enroll more than 1,000 participants.

Million Veteran Program and COVID-19—VA's Million Veteran Program (MVP) has deployed a COVID-19 questionnaire to participants to collect information about their experience with COVID-19. In addition, MVP has prioritized a series of research questions to examine the genetic basis of infection by the SARS CoV-2 virus; complications of infection; disease severity and outcomes; and

response to various treatments/medications (pharmacogenomics). MVP will also seek to identify disease mechanisms and new treatment targets for COVID-19. Given MVP's racially and ethnically diverse participant population (~ 20% African American and 7% Hispanic), the influence of race and ethnicity on disease susceptibility, severity, and outcomes will be an integral part of the analyses.

Synthesizing evidence—Researchers from the VA Evidence Synthesis Program are working to synthesize publications about the novel coronavirus and COVID-19, and to translate that information into usable guidance for clinicians.

These and many other reports can be found on a website ESP has stood up to catalog evidence reviews and make them widely available. ESP's goal is to capture the work of evidence synthesis groups in the U.S. and around the world to maximize these groups' collective contributions to the COVID-19 response and avoid duplication of effort. To date, the ESP group itself has completed four rapid-response reports: "Risk of Transmitting COVID-19 During Nebulizer Treatment"; "Antithrombotic Therapies for COVID-19 Disease"; "COVID-19: Intensive Care Unit Length of Stay and Ventilation Days"; and "Corticosteroid Therapy & ARDS for COVID-19 Infection." More reports are in the works.

The VINCI team, with Central IRB approval, is participating in the Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program, an international, interdisciplinary collaborative to maximize the value of health data through large-scale analytics. All its solutions are open-source. OHDSI is running studies focusing on 1) characterizing COVID-19 patients based on new data coming in; 2) creating predictive models based on historical data (for example, from flu pandemics) and testing them out on new COVID-19 data; and 3) using historical data to answer relevant safety questions. The group is also performing literature reviews and defining phenotypes. More information is available from Dr. Scott DuVall at scott.duvall@va.gov.

Facilitating access to investigational drugs under compassionate use—This allows access, through a research pathway, to drugs that are not yet available on the market. The team has streamlined and organized a central assistance process for VA medical centers seeking expanded access (a.k.a. compassionate use) under FDA rules to investigational drugs for COVID-19 treatments.

Examining off-label use of existing approved drugs—Drugs that are already FDA-approved for other health conditions are being used to treat COVID-19. ORD can contribute to the understanding of whether these drugs are safe and useful by helping to track data on prescriptions, side effects, and outcomes; and working with VHA Public Health Surveillance and Research in Palo Alto and Pharmacy Benefits Management on longitudinal tracking of data on COVID-19 patients, including those prescribed off-label drugs.

Research map—The image below is part of a multi-slide map being used by ORD to plot COVID-19 VA research activity. The blue circles show sites that have reported R&D Committee-approved COVID-19 studies to ORD (regardless of funding source) through the SharePoint portal, with larger circles indicating more activity at those respective sites. The weekly research map also shows all of the sites participating in the convalescent plasma expanded access program. (Please note that the states of Hawaii and Alaska are not shown on this version due to graphical limitations. There are currently no COVID-19 activities reported from those states' R&DCs.)

FAQs

"FAQs Regarding COVID-19 Impacts on Research," based on questions from the field, was last updated June 22 (can be found as "ORD COVID-19 FAQs v.3.2" on SharePoint). A sample question is provided below. Please check the full document for guidance before emailing your question to ORDCOVID19@va.gov. Also, note that ORPP&E's FAQs on the Mayo Clinic Expanded Access program are also on SharePoint, and animal research FAQs are on the VA research website.

Should the facility purchase all personal protective equipment (PPE) required to enhance safety and protection for staff and patients/research participants as a result of coronavirus with available COVID-19 Supplemental funding?

Yes, to maintain the locally established standards of protection, the facility should procure and purchase all PPE for all staff and patients/research participants using the COVID-19 Supplemental funding. To maintain continuity, it is important that the same guidelines applied to medical care regarding PPE needs are also applied to the research community. Should the nature of a particular research protocol require enhanced PPE above this standard level provided by the facility, the respective research protocol can bear the cost of the enhanced PPE after concurrence from the facility.

Upcoming Events

Webinar: "VA Informatics and Computing Infrastructure: Updates to the VA COVID-19 Shared Data Resource and its Use for Research," Tuesday, June 23, 2020, 2:00 – 3:00 pm ET. Since the introduction to the VA COVID-19 Shared Data Resource, the research and operations communities have provided feedback on additional features and format that can enhance value. In this Cyberseminar, Drs. Scott DuVall and Jeffrey Scehnet will present the changes, organization of data, and how researchers can continue to use the VA COVID-19 Shared Data Resource for answering important COVID-19-related questions. Register here.

Featured Links

VA Research on COVID-19—An external webpage, on the VA Research website, providing an overview of VA's research response to the pandemic.

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)—The best place to learn about this wide-reaching NIH effort. VA is one of the seven government leadership organizations listed on the site.

ORD Informational Resources and Contact List—A handy listing for the VA research community of ORD web pages, SharePoint sites, and email points of contact for a variety of matters, covering COVID-19 research and other areas.

Employee Support Resources—Resources to support the mind, body and soul such as meditation, relaxation techniques, breathing exercises, yoga, and more. Sponsored by the VA offices of Mental Health and Suicide Prevention, Patient Centered Care and Cultural Transformation, National Center for Organization Development, Patient Experience Directorate of the Veteran Experience Office, and Chaplain Services.

VHA-Wide DUSHOM COVID-19 Memorandums—Internal SharePoint site housing all DUSHOM memorandums.

EIC Video Messages—Messages from the VHA Executive in Charge and Office of the Under Secretary for Health.

VA Insider COVID-19 Page—The COVID-19 Coronavirus News and Information VA Insider page, an internal resource for all VA staff.

VHA High Consequence Infection (HCI) Preparedness Program Novel Coronavirus Infection Site—This internal SharePoint site is VA's central location for staff to find the latest COVID-19 policies, guidance, and training resources.

COVID-19 Reviews—Website built and maintained by the VA Evidence Synthesis Program to capture the work of evidence synthesis groups worldwide.

Additional Links

- Office of Research Protections, Policy and Education
- VA Animal Research Program
- Office of Research Oversight COVID-19 SharePoint site
- Department of Veterans Affairs Public Health
- Department of Homeland Security Science & Technology Directorate Master Question List for COVID-19
- Centers for Disease Control and Prevention
- National Institutes of Health
- NIH National Library of Medicine - LitCovid
- World Health Organization - Global Research on COVID-19
- Department of Defense
- Johns Hopkins University Coronavirus Map
- Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19
- VA Posters and Fact Sheets
- Guidance for HR flexibilities for employees impacted by COVID-19

To communicate with ORD about COVID-19: ORDCOVID19@va.gov
To access ORD resources on COVID-19:

https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19.

If you would prefer to not receive these messages in the future please email ORDCOVID19@va.gov.

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